

Exhibit G

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION

4 - - -

5
6 IN RE: ETHICON, INC. : MDL NO. 2327
7 PELVIC REPAIR SYSTEM, :
8 PRODUCTS LIABILITY :
9 LITIGATION :

10 - - -

11 AND VARIOUS OTHER CROSS-NOTICED ACTIONS

12 - - -

13 May 22, 2013

14 - - -

15 CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

16 Videotaped 30(b)(6) deposition of
17 DANIEL F. BURKLEY, MS taken pursuant to notice, was
18 held at the law offices of Riker Danzig Scherer
19 Hyland & Perretti LLP, Headquarters Plaza, One
20 Speedwell Avenue, Morristown, New Jersey, beginning
21 at 9:23 a.m., on the above date, before Ann Marie
22 Mitchell, a Federally Approved Certified Realtime
23 Reporter, Registered Diplomate Reporter and Notary
24 Public for the State of New Jersey.
25

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Testimony of: DANIEL F. BURKLEY, MS
By Mr. Anderson 8

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E X H I B I T S
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NO.	DESCRIPTION	PAGE
T-268	Curriculum Vitae, 3 pages	11
T-269	E-mail chain, top one dated 03 Apr 2009, Bates stamped ETH.MESH.02184435 and ETH.MESH.02184436	24
T-270	Johnson & Johnson Credo, 1 page	34
T-271	"Our Ethical Code for the Conduct of Research and Development," 1 page	69
T-272	E-mail chain, top one dated 01 Mar 2012, Bates stamped ETH.MESH.07226377 through ETH.MESH.07226379	95
T-273	E-mail chain, top one dated 29 Feb 2012, Bates stamped ETH.MESH.04038180 and ETH.MESH.04038181	132
T-274	E-mail chain, top one dated 05 Mar 2012, Bates stamped ETH.MESH.04937874 through ETH.MESH.04937876	165

1	T-275	Response to e-mail from C. Huntington, March 6, 2012, Bates stamped ETH.MESH.07212397 and ETH.MESH.07212398	169
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4	T-276	Memo dated March 12, 2012, Bates stamped ETH.MESH.07205369 and ETH.MESH.07205370	187
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6	T-277	Article entitled "Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants," Arnaud Clave, et al., 10 pages	198
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9	T-278	E-mail chain, top one dated 07 Mar 2012, Bates stamped ETH.MESH.07226404 and ETH.MESH.07226405	198
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11	T-279	Interim report mesh explants pelvic floor repair, April 2008, Bates stamped ETH.MESH.00006636	267
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13	T-280	Intermediate Report -- Prolapse Mesh Explants 6/2009, Bates stamped ETH.MESH.02157879 and ETH.MESH.02157880	275
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Confidential - Subject to Protective Order

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DEPOSITION SUPPORT INDEX

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1 THE VIDEOGRAPHER: We're now on the
2 record. My name is David Lane. I'm a videographer
3 for Golkow Technologies. Today's date is May 22,
4 2013, and the time is 9:23 a.m. This video
5 deposition is being held in Morristown, New Jersey
6 In Re: Ethicon, Inc. Pelvic Repair Systems. Our
7 deponent today is Daniel Burkley.

8 Counsel will be noted on the
9 stenographic record.

10 The court reporter today is Ann Marie
11 Mitchell, and will now swear in the witness.

12 - - -

13 DANIEL F. BURKLEY, MS, after having
14 been duly sworn, was examined and
15 testified as follows:

16 - - -

17 THE VIDEOGRAPHER: Please begin.

18 MR. HALL: I would like to note
19 before we begin that Altman, McGuire, McClellan and
20 Crum, P.S.C., as well as Dr. Rick McClellan
21 individually, have objected to the cross-notice of
22 these video depositions but that that objection
23 hasn't yet been heard by the Court.

24 MR. ANDERSON: So noted.

25 MR. HALL: Thank you.

1 - - -

2 EXAMINATION

3 - - -

4 BY MR. ANDERSON:

5 Q. Good morning, Mr. Burkley.

6 A. Good morning.

7 Q. Good to see you again. I took your
8 deposition back in October of 2012, probably right
9 here in this same office.

10 Do you recall that?

11 A. Yes, I do.

12 Q. And at the beginning you may recall
13 that I gave a few ground rules. And since I know
14 now that you've been through the deposition process,
15 the only one that I would reiterate is that if you
16 answer one of my questions, we're going to assume
17 that you understood it unless you tell me I need to
18 clarify it or otherwise restate it; is that fair?

19 A. Yes.

20 Q. You have been an employee at Ethicon
21 since 1979. Correct?

22 A. That is correct.

23 Q. So you're in your 34th year?

24 A. Yes.

25 Q. And you were a senior scientist in

1 corporate product characterization for many years,
2 and then at some point in time, corporate product
3 characterization was reorganized within R&D.

4 Correct?

5 A. That's correct.

6 Q. And that department is now called
7 analytical characterization; is that correct?

8 A. That's one of the departments that
9 spun off from corporate product characterization.

10 Q. And are you currently a senior
11 scientist in the analytical characterization
12 department?

13 A. My current title is principal
14 scientist.

15 Q. And you operate the infrared optical
16 microscopy lab, and you characterize polymers,
17 materials, competitor products, as well as
18 characterizing the causes of failure on return
19 product complaints for quality improvement; is that
20 correct?

21 A. That is correct.

22 Q. And you are the person at
23 Ethicon/Johnson & Johnson with primary
24 responsibility for performing optical microscopy
25 analysis of surgical meshes in terms of the

1 analytical characterization group; is that correct?

2 MR. DAVIS: Object to the form.

3 THE WITNESS: I am one such resource.

4 I'm not the only resource.

5 BY MR. ANDERSON:

6 Q. At the Ethicon Somerville location,
7 who other than yourself currently performs optical
8 microscopy or infrared analysis of surgical meshes?

9 A. I would be one such individual that
10 performs infrared analysis from a research point of
11 view. As far as optical microscopy, there are other
12 departments that do have optical microscopes, so
13 it's conceivable that they could do optical
14 measurements on meshes or other devices besides
15 myself.

16 Q. And I appreciate that it may be
17 conceivable, but in all practical purposes, can you
18 and I agree that you are the primary person who
19 performs optical microscopy and IR analysis of
20 Ethicon surgical meshes currently?

21 A. For analytical characterization, yes,
22 I do.

23 Q. I will mark my first T exhibit as
24 Exhibit Number 268, which was sent to us and
25 represented as your current CV.

1

- - -

2

(Deposition Exhibit No. T-268,

3

Curriculum Vitae, 3 pages, was marked for

4

identification.)

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6

BY MR. ANDERSON:

7

Q. Do you have that in front of you?

8

A. I do.

9

Q. And is that in fact a current copy of

10 your CV or resume?

11

A. Yes, it is.

12

Q. Have there been any significant

13 additions, changes, modifications since we last met

14 in October of last year?

15

A. I believe that this is the updated

16 version since October.

17

Q. Right. And I guess I didn't bring

18 the other one to compare.

19

I was just wondering if anything

20 comes to mind of significance in your CV that has

21 changed or been added since we met in October?

22

A. Oh, since we met in October. Well,

23 I've updated it, because I believe the previous one

24 was significantly older.

25

Q. Yes. I remember you saying that at

1 the time.

2 A. So yeah. So I have updated it up to
3 at least 2012.

4 Q. I notice under your "Publications"
5 and ("Articles)," you have, on the second page of
6 your CV, under the third publication listed --
7 actually, let's make it the fourth one, the last
8 one.

9 A. Uh-huh.

10 Q. "In-Vitro Antimicrobial Evaluation of
11 Coated VICRYL Plus Antibacterial Suture (Coated
12 Polyglactin 910 with Triclosan) Using Zone of
13 Inhibition Assays," in the publication Surgical
14 Infections.

15 A. Yes.

16 Q. Is that a peer-reviewed publication?

17 A. I can't answer that question, I don't
18 know.

19 Q. Do you have a copy of that in your
20 files somewhere that you could provide to us?

21 A. I had a copy that I had in my office
22 last year, but I've changed locations and I don't
23 believe I have it anymore.

24 Q. Would you do me a favor and agree
25 that after the deposition, at a reasonable point in

1 time, that you would go and do a thorough search to
2 see if you can find a copy of that --

3 A. Sure.

4 Q. -- either in electronic form or hard
5 copy and provide that to counsel?

6 A. Okay.

7 MR. ANDERSON: And, Counsel, if I
8 could just follow-up with you after the deposition,
9 I'll follow up with you after the deposition and
10 I'll just send you an e-mail, if that's okay, and
11 remind us that we're going to have a search for
12 that. Okay?

13 MR. DAVIS: Sure.

14 MR. ANDERSON: Thank you.

15 BY MR. ANDERSON:

16 Q. And if you look at the next page, I
17 see, one, two, three, four, five articles, and the
18 first author is Meng Deng?

19 A. Yes.

20 Q. Who is also an Ethicon employee.

21 A. He is.

22 Q. Correct?

23 These publications, one is in the
24 publication Biomaterials.

25 That's a peer-reviewed publication?

1 A. I believe so.

2 Q. Do you have a copy of any of these
3 publications listed on page 3 of your CV?

4 A. I may have copies of the abstract but
5 not the actual articles.

6 Q. Last time you and I met, we talked
7 about the fact that Johnson & Johnson/Ethicon has a
8 database of documents and scientific literature.

9 A. They do.

10 Q. Given that yourself and Meng Deng
11 were authors in these publications, would you
12 anticipate that Johnson & Johnson/Ethicon would have
13 this contained within this scientific literature
14 database?

15 A. They may. They're not Ethicon
16 documents, per se, but it's possible that these
17 articles would be in there.

18 Q. And not all articles, scientific
19 journals, that are in Johnson & Johnson/Ethicon's
20 database are Johnson & Johnson/Ethicon studies.
21 Correct?

22 A. I don't know the answer to that
23 question.

24 Q. So there's the one article at the top
25 of page 3 of your resume published in Biomaterials.

1 The next one is -- well, strike that. Let me go
2 back to that first one.

3 The title is "Effect of Load and
4 Temperature on in-vitro Degradation of
5 Poly(glycolide-co-L-lactide) Multifilament Braids."

6 Do you see that?

7 A. I do.

8 Q. Was that a study that was done
9 internally at Ethicon?

10 A. Yes.

11 Q. What was the purpose of doing that
12 study?

13 A. To gain a better understanding of the
14 absorbable polymer system based on glycolide lactide
15 under in vitro conditions.

16 Q. And what in vitro conditions were
17 used?

18 A. I'd have to refresh my memory with
19 the article. I didn't actually conduct the in vitro
20 experiments.

21 Q. What was your role in the scientific
22 research analysis and conclusions that may have been
23 reached in that Biomaterials publication?

24 A. I provided SEM analysis of test
25 articles after they were exposed to in vitro

1 conditions.

2 Q. What type of in vitro conditions?

3 Are we talking humans? Are we talking animals?

4 A. Well, in vitro would be artificial.

5 Q. Oh, in vitro, I'm sorry. Yes.

6 So would that have been in the

7 laboratory in mechanical conditions or in wet

8 solutions, what?

9 A. They would have been in buffered

10 solutions.

11 Q. Was this in relation to the Vypro

12 mesh?

13 A. I don't know specifically if it was

14 related to mesh.

15 Q. Is that particular chemical that's

16 listed there, the polyglycolide-Co-L-lactide, known

17 by other names?

18 A. Yes. Known as polyglactin 910.

19 Q. And polyglactin 910 is the absorbable

20 component in the absorbable suture Vicryl. Correct?

21 A. That is correct.

22 Q. Which is the absorbable component,

23 along with polypropylene, in the hernia mesh known

24 as Vypro made by Ethicon/Johnson & Johnson.

25 Correct?

1 A. That is correct, yes.

2 Q. Polyglactin 910 is also an additive
3 component to TVT SECUR, a sling product for SUI made
4 by Ethicon and Johnson & Johnson. Correct?

5 A. Yes, it is.

6 Q. That publication was in 2005, and in
7 the next publication in 2006, also with the same
8 authors except for Xu, X-U, it also appears to
9 address in vitro degradation of polyglactin 910.

10 Am I reading that correctly?

11 A. Yes.

12 Q. This appears to be a book chapter,
13 because it has, "chapter titled: Degradation
14 Mechanisms."

15 Would that be correct?

16 A. I believe so, yes.

17 Q. And you don't know if you still have
18 a copy of that book?

19 A. I never got a copy of the book.

20 Q. Okay.

21 Out of those authors, who is the most
22 likely person -- well, let me back up a minute and
23 strike that question.

24 J. Zhou, is that how you pronounce
25 Z-H-O-U?

1 A. I believe it's pronounced Zhou.

2 Q. Zhou. Interesting.

3 And then there's G. Chen.

4 Are Zhou and Chen also Ethicon
5 employees?

6 A. They are.

7 Q. Who of those authors is the most
8 likely to have the book from which this chapter,
9 Degradation Mechanisms, is born?

10 A. That would be the first author.

11 Q. So Meng Deng is the most likely
12 person to have a copy of these five -- yes, five
13 articles on page 3 of your resume?

14 A. Yes. As the principal author, I
15 would expect him to have a copy.

16 Q. The next article or publication
17 underneath that one is in Polymer Preprints.

18 Do you know if that's a peer-reviewed
19 publication?

20 A. I believe it is.

21 Q. You know what I mean by peer
22 reviewed. Correct?

23 A. Yes.

24 Q. Again addressing polyglactin 910 in
25 vitro degradation?

1 A. Yes.

2 Q. The next article also addresses
3 polyglactin 910 degradation that was published in
4 Acta Biomaterialia?

5 A. Yes.

6 Q. And Acta Biomaterialia is a
7 publication by a materials industry group or
8 corporation. Correct?

9 A. I don't know that for a fact.

10 Q. Have you heard of the gold medal
11 award that Acta Biomaterialia gives out each year to
12 some person that they consider to be a leading
13 professional in the field of biomaterial research?

14 A. I'm unfamiliar with that award.

15 Q. The next and last article is also
16 Polymer Preprints, dealing with polyglactin 910
17 again. Correct?

18 A. Yes.

19 Q. In any of these -- strike that.

20 In all of these publications and the
21 work that went into them, were you performing
22 basically the same duties that you mentioned before,
23 that you were doing SEM analysis of test articles
24 and looking at the in vitro conditions of
25 polyglactin 910 in buffered solutions?

1 A. My role would have been to do the SEM
2 examinations of the test articles after they had
3 been exposed to in vitro conditions.

4 Q. So did you do SEMs before and after?

5 A. In most instances, I believe I did.

6 Q. Was there any attempt in the research
7 that went into these publications regarding the
8 degradation of polyglactin 910 to look at and
9 analyze the degradation of any other material other
10 than polyglactin 910? For example, if this was
11 involving the Vypro product, did you look at the
12 degradation in vivo of both the Vicryl as well as
13 the polypropylene?

14 MR. DAVIS: Object to the form.

15 THE WITNESS: No, I do not believe
16 so.

17 BY MR. ANDERSON:

18 Q. In your 34 years at Ethicon, have you
19 ever been asked to perform SEM analysis of
20 Ethicon/Johnson & Johnson polypropylene surgical
21 mesh?

22 A. Yes, I've looked at surgical mesh.

23 Q. And have you ever in those 34 years
24 been asked to conduct a study to look at in vivo or
25 in vitro degradation of polypropylene other than

1 your seven-year dog study?

2 MR. DAVIS: Object to the form.

3 THE WITNESS: No, I have not
4 conducted such a study or have -- nor have I been
5 asked to conduct such a study.

6 BY MR. ANDERSON:

7 Q. Have you ever felt the need during
8 your 34 years at Ethicon/Johnson & Johnson to go to
9 your superiors or your colleagues within your
10 company and suggest that a polypropylene degradation
11 study be performed, either in vitro, in vitro or
12 both?

13 A. No, I have not taken such an
14 initiative by myself. That would be primarily a
15 clinical concern, and such a study would best be
16 performed under clinical direction or preclinical
17 direction.

18 Q. It may be performed under preclinical
19 direction, but as we've seen with these studies and
20 other things that are done within your company in
21 terms of analytical characterization, you would be
22 the one -- or strike that.

23 Even though it may be of clinical
24 concern, you are often asked to perform SEM or IR
25 analysis on products within the company, even if

1 it's pertaining to a clinical matter. Correct?

2 MR. DAVIS: Object to the form.

3 THE WITNESS: There have been
4 instances when I've been asked to perform that as a
5 resource, yes.

6 BY MR. ANDERSON:

7 Q. So just because it may be direct --
8 strike that.

9 Just because a particular study might
10 be directed by clinical, that doesn't mean you
11 wouldn't be involved. Correct?

12 A. I'm sorry, could you rephrase that
13 again?

14 Q. Sure.

15 We're talking now about whether or
16 not you were ever asked to perform any sort of
17 analysis during your 34 years at Ethicon of
18 polypropylene mesh or sutures manufactured by J&J
19 and Ethicon or its competitors --

20 A. Yes.

21 Q. -- to look at either in vitro or in
22 vivo degradation, and you said you'd never been
23 asked to do that.

24 My follow-up question was, just to
25 put us back into our frame of reference --

1 A. Right.

2 Q. -- have you ever asked or addressed
3 the issue with your colleagues or your superiors
4 within Ethicon as to whether or not a degradation
5 study should be performed on polypropylene?

6 A. No, I've not taken such an
7 initiative.

8 Q. In your 34 years at Ethicon, are you
9 aware of anyone within Johnson & Johnson and Ethicon
10 who took the initiative to do a degradation study in
11 vitro or in vivo of Ethicon/Johnson & Johnson's
12 polypropylene mesh or sutures?

13 MR. DAVIS: Object to the form.

14 THE WITNESS: I'm only familiar with
15 the dog study that involved Prolene suture and at
16 least two other competitors and perhaps another
17 suture.

18 BY MR. ANDERSON:

19 Q. And that was 25 years ago?

20 A. I believe that was started around
21 1985, yeah.

22 Q. So it was almost 30 years ago. Okay.
23 Other than that one suture study in a
24 dog -- and what part of the dog was that in?

25 A. I don't know specifically.

1 Q. It was cardiac, wasn't it? Does that
2 refresh your memory?

3 A. Yeah, I believe it was a cardiac.

4 Q. So other than a cardiac suture in a
5 dog heart in 1985, just to make sure we're clear for
6 the record, you're not aware in your 34 years at
7 Ethicon of anyone at Ethicon or Johnson & Johnson
8 initiating a degradation study of its polypropylene
9 sutures or meshes; is that correct?

10 MR. DAVIS: Object to the form.

11 THE WITNESS: I personally am not
12 aware of any such studies, no.

13 - - -

14 (Deposition Exhibit No. T-269, E-mail
15 chain, top one dated 03 Apr 2009, Bates
16 stamped ETH.MESH.02184435 and
17 ETH.MESH.02184436, was marked for
18 identification.)

19 - - -

20 BY MR. ANDERSON:

21 Q. Handing you what we will mark as
22 Plaintiff's Exhibit 269, T-269. I'm just going to
23 reference the second page of the document. The last
24 four of the Bates on the cover are 4435.

25 I'm just going to reference the last

1 paragraph on page 2, which ends in 4436.

2 By way of reference, if you turn --
3 and I apologize, if you'll turn back to the front
4 page just to get us oriented, the -- about a quarter
5 of the way down on the page, it has "FYI," and then
6 underneath that it says, "Mark Stachowski."

7 Who was he? What was his title in
8 2009 at Ethicon?

9 A. He was an associate -- excuse me --
10 an associate director of analytical
11 characterization.

12 Q. Was he a colleague, a direct report,
13 a supervisor?

14 A. He was basically the department
15 manager.

16 Q. So would he have been your boss, your
17 supervisor?

18 A. Yes.

19 Q. And this e-mail was sent on April 1,
20 2009, correct, just to orient us?

21 A. That's the date of the e-mail, yes.

22 Q. So just want to turn to the second
23 page, and the last paragraph.

24 Are you with me, where it begins,
25 "Additionally, Daniel Burkley"?

1 A. Yes.

2 Q. "Additionally, Daniel Burkley, M.S.,
3 will report to me and lead an increased focus in
4 Microscopy, including but not limited to SEM," and
5 that's scanning --

6 A. Electronic.

7 Q. -- electron microscopy, "AFM."
8 AFM, which is --

9 A. Atomic force microscopy.

10 Q. "IR," infrared. Correct?

11 A. Yes.

12 Q. "Microscopy and correlation with," is
13 it Raman?

14 A. Raman.

15 Q. "Raman Microscopy."

16 What is AFM? I guess a better way of
17 saying it is, I'm familiar with SEM, I'm familiar
18 with AR and I'm vaguely familiar with AFM, but I'm
19 not with Raman at all. So I was going to have you
20 explain what AFM is, and then we'll do Raman.

21 A. Oh. AFM, again, stands for atomic
22 force microscopy. It's a surface examination
23 technique where you use a cantilever, which is
24 basically a very small, minute mechanical pointer
25 with a very fine tip to basically trace the

1 topography. And basically the readings of that, in
2 terms of how high or how low the needle goes, is
3 basically converted to a surface map. And that
4 basically is the equivalent image that you would
5 have -- you would see to compare with either optical
6 or SEM.

7 Q. So if it was a smooth, flat surface,
8 the readout would be a smooth, flat line; whereas if
9 it was a rough or undulating surface, then you would
10 have a readout that would mimic the topographical
11 nature of the device that you're --

12 A. Correct.

13 Q. Okay.

14 So, for instance, if it was a
15 surgical mesh that you were performing AFM analysis
16 on, if it was a smoother mesh, that would give you a
17 readout with a more flat line, and if it was a mesh
18 that was -- had a rougher topography, if you will,
19 then it will give you a readout that would mimic
20 that. Correct?

21 A. Yes.

22 Q. What's the purpose of performing AFM
23 as you understand it for surgical meshes at
24 Ethicon/Johnson & Johnson?

25 A. I am not --

1 MR. DAVIS: Object to the form.

2 THE WITNESS: I'm not aware of any
3 AFM studies on surgical meshes.

4 BY MR. ANDERSON:

5 Q. I guess that would have been a better
6 question.

7 Do you perform AFM on surgical
8 meshes?

9 A. I do not.

10 Q. What is Raman microscopy?

11 A. Raman microscopy is in many ways a
12 counterpart to infrared microscopy, where Raman is
13 used instead of infrared. Raman spectroscopy
14 measures vibrations of bonds that have no dipole
15 moment, whereas infrared measures the vibrations of
16 bonds that do exhibit a dipole moment. So in many
17 ways, Raman is a complimentary technique to
18 infrared.

19 Q. Explain, please, what a dipole moment
20 is?

21 A. In a molecular environment or in a
22 molecular structure, you have atoms that are bonded.
23 For most organic materials, you're talking about
24 carbon combined with oxygen or nitrogen or hydrogen.
25 And each of the atoms has different

1 electronegativity. When an atom is bonded to
2 another atom that's of the same type, such as carbon
3 to carbon, there is no net dipole. There is no net
4 difference in electronegativity. When you're --
5 when a carbon is bonded to, say, an oxygen, oxygen
6 hides a higher electronegativity. It would,
7 therefore, tend to draw electrons more around the
8 oxygen atom than for the carbon. That would then
9 exhibit a dipole moment.

10 Q. Do you perform Raman microscopy on
11 polypropylene?

12 A. I have not performed Raman
13 spectroscopy or Raman microscopy.

14 Q. Would Raman microscopy be an analysis
15 that would be helpful in determining whether or not
16 the molecular bonds of polypropylene exhibit
17 carbonyls under various conditions?

18 A. It could possibly be used for that.
19 The sensitivity would be weak, but it still may pick
20 up some.

21 Q. What would be the better test in
22 order to look for carbonyls in terms of molecular
23 analysis of polypropylene under certain conditions?

24 A. Infrared would be a more sensitive
25 test as compared to Raman.

1 Q. And what's the difference between IR,
2 infrared, and FTIR, Fourier?

3 A. The Fourier transform, which is what
4 FT stands for, that technique was developed in the
5 late '70s/early '80s. And it was a revolutionary
6 technology that enhanced infrared in terms of both
7 the speed of which it can scan and could also take
8 advantage of that by increasing the signal to noise
9 based on the square root of the number of scans it
10 took. I can go into the theory if you wish.

11 Q. More important at this point in time
12 is to find out whether or not you have been asked to
13 perform FTIR analysis of any of Johnson &
14 Johnson/Ethicon's polypropylene sutures or meshes?

15 A. Yes.

16 Q. And under what circumstances have you
17 been asked to perform FTIR analysis of polypropylene
18 manufactured by Ethicon and Johnson & Johnson?

19 A. Primarily for material
20 identification.

21 Q. Meaning by that, if I'm understanding
22 you correctly, that you've been asked at times to
23 perform FTIR analysis of a particular polypropylene
24 product in order to determine if it is what it's
25 supposed to be. Correct?

1 A. Yep. That's one example, yes.

2 Q. Is this our Prolene suture or is this
3 some other manufacturer's polypropylene suture.
4 Correct?

5 A. Yep, that's another example.

6 Q. Is it correct that you have never
7 been asked nor have you taken upon yourself to
8 perform FTIR analysis of polypropylene meshes or
9 polypropylene sutures either manufactured by
10 J&J/Ethicon or a competitor for looking at
11 degradation of the polypropylene?

12 A. I have been asked to look at
13 explanted material.

14 Q. On how many occasions?

15 A. Well, the one that I remember most
16 clearly would have been the dog study.

17 Q. Since the dog -- strike that.
18 Since the time of the completion of
19 the dog study in 1985, have you been asked by anyone
20 at Ethicon and Johnson & Johnson or taken it upon
21 yourself to perform FTIR analysis of polypropylene
22 fibers, either manufactured by Johnson &
23 Johnson/Ethicon and/or a competitor, for purposes of
24 looking at surface degradation?

25 MR. DAVIS: Object to form.

1 THE WITNESS: I don't recall. If I
2 have, it would have been in that same time frame as
3 the dog study. So certainly not -- nothing in any
4 recent history, like within the last 15 or so years.
5 But it's possible I may have looked at some material
6 in the '80s.

7 BY MR. ANDERSON:

8 Q. Now, you have done FTIR analysis for
9 specification verification on certain mesh products
10 manufactured by Johnson & Johnson and Ethicon.
11 Correct?

12 A. Well, material identification tests,
13 it's possible a protocol may have required an
14 identity as a specification. And I've certainly
15 looked at raw materials.

16 Q. What was the purpose of looking at
17 the raw materials under FTIR analysis?

18 A. Primarily part of research, whether
19 they were compounding new materials or making blends
20 or making devices and wanted to look for evidence
21 of, you know, material identification and/or to look
22 to see if there were additives present or residual
23 lubricants.

24 Q. In other words, if I'm hearing you
25 correctly, there have been times that you've been

1 asked to perform FTIR analysis on certain
2 polypropylene mesh or mesh fibers manufactured by
3 Johnson & Johnson and Ethicon in which you would
4 look to see whether or not certain manufacturing
5 additives were there and in what amount. Yes?

6 A. Well, not from a manufacturing
7 environment. From a research environment, a
8 development environment.

9 Q. And when you've been asked to use
10 FTIR on residuals, by residuals do you mean
11 surfactants and other things that may have been
12 added to the manufacturing process to see if they
13 are there or if they are there, in what amount?

14 MR. DAVIS: Object to form.

15 THE WITNESS: Most applications would
16 involve residual lubricants. There have been a
17 couple of troubleshooting -- work that I've done for
18 troubleshooting purposes to determine -- to try to
19 solve a manufacturing issue, such as the fiber
20 feeling sticky, for example, and trying to determine
21 what could cause that.

22 BY MR. ANDERSON:

23 Q. Are you familiar with the -- strike
24 that.

25 Are you familiar with the Johnson &

1 Johnson credo?

2 A. Yes.

3 Q. Do you pronounce it credo or credo?

4 A. Credo.

5 - - -

6 (A discussion off the record
7 occurred.)

8 - - -

9 (Deposition Exhibit No. T-270,
10 Johnson & Johnson Credo, 1 page, was
11 marked for identification.)

12 - - -

13 BY MR. ANDERSON:

14 Q. I'm going to hand you Plaintiff's
15 T-270. I printed this off Johnson & Johnson's
16 website.

17 Is that the credo that you're
18 familiar with?

19 A. Yes. It's gone through a few
20 iterations over the duration of my employment, but
21 it's essentially the same.

22 Q. So since you became employed at
23 Johnson & Johnson/Ethicon in 1979, there has always
24 been a credo in some form in place?

25 A. There has been, yes.

1 Q. As you look at this one, is this what
2 you believe to be the current version of the credo?

3 A. This appears to be current, yes.

4 Q. Even though it says "Johnson &
5 Johnson" at the bottom, it applies to other
6 companies owned or operated by Johnson & Johnson
7 like Ethicon. Correct?

8 A. That is correct.

9 Q. So if we're talking about the Johnson
10 & Johnson credo, we're also talking about the
11 Ethicon credo. Correct?

12 A. Yes.

13 Q. And that's whether it's a Johnson &
14 Johnson or Ethicon facility in the United States or
15 at any other of its facilities worldwide. Correct?

16 A. I believe so, yes.

17 Q. This is actually on the wall, as soon
18 as you come in to Johnson & Johnson. Correct?

19 A. It is.

20 Q. When you walk into your facilities in
21 Somerville, is it on the wall there?

22 A. It's on at least one wall.

23 Q. When was the last time you read the
24 credo?

25 A. I believe it was last year.

1 Q. Before your last deposition?

2 A. No. It was before, a credo survey.

3 Q. What is a credo survey?

4 A. At periodic times, Johnson & Johnson
5 conducts surveys of its employees with respect --
6 which they call a credo survey. And they basically
7 ask a number of questions that -- relating to the
8 credo to get employee feedback.

9 Q. Is that sent out via e-mail or in
10 what form of media is the survey conducted?

11 A. It's electronic. There's usually an
12 e-mail notification along with a link.

13 Q. And do you follow that link in order
14 to go through a series of questions that you answer?

15 A. Yes.

16 Q. Related to the credo?

17 A. Yes. Years ago, it used to be
18 physical. In other words, they'd get the employees
19 together and you'd actually fill it out by hand.

20 Q. How long have you been doing it
21 electronically approximately?

22 MR. DAVIS: Object to the form.

23 THE WITNESS: I'm going to say maybe
24 six to eight years.

25 BY MR. ANDERSON:

1 Q. Is it done at least once a year, this
2 Johnson & Johnson credo survey?

3 A. I don't know if it's done at least
4 once at year. It's done at most once a year.

5 Q. Is that an opportunity for employees
6 of Johnson & Johnson/Ethicon to state whether or not
7 they believe that the credo is being followed --

8 A. It is --

9 Q. -- or violated in some manner?

10 A. Yeah. It's an opportunity for the
11 employees to express their opinions, not only on
12 questions, but there are, at the end of the surveys,
13 usually a comments section. So if they have
14 anything specific they want to say, they may.

15 Q. So it's a way for employees to give
16 feedback to management in terms of whether or not
17 the employees feel that Johnson & Johnson is in fact
18 following its credo. Correct?

19 A. Yes. It's an opportunity.

20 Q. If you look at that first -- those
21 first two sentences, under "Our Credo," "We believe
22 our first responsibility is to the doctors, nurses
23 and patients, to mothers and fathers and all others
24 who use our products and services. In meeting their
25 needs everything we do must be of high quality."

1 Did I read that correctly?

2 A. Yes.

3 Q. And do you believe that?

4 A. I do.

5 Q. Do you believe that your colleagues
6 follow that credo?

7 MR. DAVIS: Object to the form.

8 THE WITNESS: In general, yes, I
9 believe they do.

10 BY MR. ANDERSON:

11 Q. So one of the things that this
12 particular part of the credo was saying is that the
13 people who use our products, their safety must come
14 first. Correct?

15 A. It doesn't say that specifically.

16 Q. Is that one of the fair
17 characterizations of this first sentence or the --
18 and the second sentence, that in terms of patients,
19 their health and safety must come first at Ethicon.
20 Correct?

21 A. We're certainly concerned about that,
22 but that's not what this document says.

23 Q. What's the primary concern at Ethicon
24 and Johnson & Johnson? Would it be profits to
25 shareholders or patient safety?

1 MR. DAVIS: Object to the form.

2 BY MR. ANDERSON:

3 Q. Or are they equal?

4 MR. DAVIS: Object to the form.

5 THE WITNESS: That's basically a
6 judgment call or an impression on my part. I don't
7 know if I can really answer what upper management's
8 primary goals are or what their relative priorities
9 are, but I do believe that they follow the spirit of
10 the credo in that we make products of high quality
11 that are safe and efficacious, and since we are a
12 private company, yeah, there is a -- there is some
13 type of profit margin that's realized.

14 BY MR. ANDERSON:

15 Q. And I appreciate you answering that.

16 My question is, what comes first,
17 patient safety or the business aspect of it, the
18 profits, or are they equal in your mind after being
19 an employee there for 34 years?

20 MR. DAVIS: Objection.

21 THE WITNESS: I can't comment on
22 that. I can't comment on what priorities they
23 assign. Certainly all those considerations are
24 taken into account, but I have no idea what the
25 relative priorities are.

1 BY MR. ANDERSON:

2 Q. In your mind, for your relative
3 priorities as a 34-year employee, when you see this
4 credo on the wall, in your mind, do you believe that
5 patient safety comes first before profits or profits
6 come before patient safety?

7 A. I don't look at it in that term.

8 Q. Well --

9 A. I don't assign a hierarchy or a
10 priority.

11 Q. So in terms of your reading of this
12 part of the credo, you don't have a feeling one way
13 or another as to whether or not patient safety
14 should come before profits of Johnson &
15 Johnson/Ethicon. Is that your answer?

16 MR. DAVIS: Object to the form.

17 THE WITNESS: No. My answer is that
18 I believe that Johnson & Johnson's products takes
19 into account patient safety, that they're
20 efficacious, that they're of high quality and that
21 they are sold and there is a profit margin realized.
22 I have no idea how high or how significant that
23 profit margin is. And I don't have a concern as to
24 what the relative priorities of those items are.
25 All I know is that they're all taken into account

1 when a product is released.

2 BY MR. ANDERSON:

3 Q. You don't have a concern as to
4 whether or not your company puts profits ahead of
5 patient safety?

6 MR. DAVIS: Object to the form.

7 THE WITNESS: Repeat that question,
8 please?

9 BY MR. ANDERSON:

10 Q. You just said, I don't have a concern
11 as to which one comes first, so I'm trying to
12 clarify --

13 A. No, no, I didn't say that.

14 Q. That's why I tried to clarify.

15 Is that what you're saying?

16 A. You're paraphrasing me. I said my
17 concern -- I don't have a concern in terms of what
18 priorities they assign. My -- I'm confident that
19 the products that are released cover safety and
20 efficacy, they're of high quality, and I do realize
21 that they recognize a profit margin, although I have
22 no idea what that is.

23 Q. So in reading back your answer, "I
24 don't have a concern in terms of what priorities
25 they" -- you mean upper level management? Who is

1 "they"?

2 A. I don't have a concern -- the --
3 well, you asked me about priorities. I don't know
4 what the priorities are. And I'm not concerned
5 about -- and I don't look at it in terms of a
6 priority-type system. All of these features are
7 taken into account when we release a product.

8 Q. So you don't have a concern as to
9 whether or not the management of Johnson & Johnson
10 and Ethicon puts profits before patient safety?

11 MR. DAVIS: Object to the form.

12 THE WITNESS: I'm confident that all
13 of those factors are taken into account.

14 BY MR. ANDERSON:

15 Q. Do you believe that that would be a
16 good part of the credo, to say that we put patient
17 safety before profits at Johnson & Johnson?

18 MR. DAVIS: Object to the form.

19 THE WITNESS: Well, I haven't been
20 given an opportunity to author for the credo, and I
21 don't feel I'm qualified to do that.

22 BY MR. ANDERSON:

23 Q. Well, now's your opportunity.

24 MR. DAVIS: Object to the form.

25 THE WITNESS: Well, I'm going to have

1 to pass on that opportunity, because I don't feel
2 comfortable doing that.

3 BY MR. ANDERSON:

4 Q. Do you believe that a company who
5 manufactures permanently implanted medical devices
6 for a woman's pelvis should put patient safety
7 before their profits?

8 MR. DAVIS: Object to the form.

9 THE WITNESS: I don't believe it has
10 to come to a decision on that.

11 BY MR. ANDERSON:

12 Q. If there's a decision as to whether
13 or not the company is going to make a profit but it
14 will come at some risk of injury to the patient, do
15 you have a feeling one way or another as to the --
16 whether the priority should be making that profit or
17 making a safer product?

18 MR. DAVIS: Object to the form.

19 THE WITNESS: I don't believe that
20 type of proposition really comes into play.

21 BY MR. ANDERSON:

22 Q. Let's assume it does. Let's assume
23 Johnson & Johnson and Ethicon, your colleagues that
24 you've worked with for 34 years, are in -- they're
25 at a decision tree, at a crossroads. If we go this

1 way, it's going to be better for our profits, but it
2 could hurt patient safety, but if we go this way, it
3 could hurt the profits vis-à-vis our competitors,
4 but it's going to make patients safer.

5 Which road should Johnson & Johnson
6 and Ethicon take?

7 MR. DAVIS: Object to the form.

8 THE WITNESS: I'm inclined to believe
9 that they would take the road that would ensure
10 patient safety.

11 BY MR. ANDERSON:

12 Q. So is it your understanding that
13 Johnson & Johnson's credo puts patient safety before
14 corporate profits, or do you not have a feeling one
15 way or another?

16 MR. DAVIS: Object to the form.

17 THE WITNESS: I believe they take a
18 balanced approach to it.

19 BY MR. ANDERSON:

20 Q. A balanced approach, meaning?

21 A. They weigh -- they have to weigh all
22 these factors.

23 Q. This is your opportunity to write
24 this part of the credo.

25 Do you believe, being involved with

1 this company as long as you have, that your credo
2 should be we put patient safety before profits
3 always?

4 MR. DAVIS: Object to the form.

5 THE WITNESS: I don't have enough
6 experience as a businessman or an owner/operator of
7 a business, even this business, to make that
8 decision on my own.

9 BY MR. ANDERSON:

10 Q. How about as a person in the
11 community, as a consumer yourself, do you believe
12 that companies should put patient safety ahead of
13 corporate profit?

14 MR. DAVIS: Object to the form.

15 THE WITNESS: I believe that
16 companies should be responsible for putting out safe
17 products.

18 BY MR. ANDERSON:

19 Q. And do you believe -- that's not an
20 answer to my question.

21 As a person in the community, as a
22 consumer yourself, do you believe that companies
23 should put patient safety ahead of corporate
24 profits?

25 MR. DAVIS: Object to the form.

1 THE WITNESS: That still puts me in
2 the role of operating a business. I'd have to -- to
3 really look at that objectively, I'd have to look at
4 myself as a business owner, and there are just a
5 number of factors and considerations that I have no
6 clue about, and, therefore, I'm just not capable of
7 adequately answering that question.

8 BY MR. ANDERSON:

9 Q. I take it from time to time you've
10 had to take medications in your life?

11 A. Yes.

12 Q. When you reach into your medicine
13 cabinet and you take down a pill bottle, do you care
14 whether or not the company who made that
15 pharmaceutical put your safety ahead of their
16 corporate profits?

17 MR. DAVIS: Object to the form.

18 THE WITNESS: I'm concerned about the
19 product's safety and, therefore, I'll read the
20 literature about it. And I'll consult with my
21 physician and get his opinion as to how safe and
22 efficacious the drug is for, you know, whatever
23 ailment I'm taking it for, so -- but I don't make
24 a -- I don't do a value proposition thought process
25 on terms of, you know, profit versus safety. The

1 product is released. It has the -- meets certain
2 guidelines, you know, it has to have some type of
3 safety information on there to support it, so -- and
4 then Johnson & Johnson I think is pretty responsible
5 about the products it releases, so that combination
6 of information is going to determine whether or not
7 I feel safe taking that drug.

8 BY MR. ANDERSON:

9 Q. When you reach into that cabinet and
10 you take that medication, do you expect that the
11 company who made that was more concerned about your
12 safety than they were about making a profit?

13 MR. DAVIS: Object to the form.

14 THE WITNESS: I don't think about
15 that consideration when I take a pill off the shelf.

16 BY MR. ANDERSON:

17 Q. Think about it right now with me, if
18 you would.

19 If you are taking a medication or
20 you're going to have a medical device implanted in
21 your body for the rest of your life, would you
22 rather the company had put patient safety first and
23 profits somewhere down below that or profits ahead
24 of your safety?

25 MR. DAVIS: Object to the form.

1 BY MR. ANDERSON:

2 Q. Which way?

3 A. I'm concerned that the product is
4 safe. The profit margin is whatever the company is
5 going to get for it. If it's a good quality
6 product, it may be -- it may very well be worth the
7 profit margin the company asks for it.

8 Q. So if you were asked to write down
9 this portion of the credo of profits versus safety,
10 am I correct that you wouldn't write Johnson &
11 Johnson should always put patient safety ahead of
12 corporate profits?

13 MR. DAVIS: Object to the form.

14 BY MR. ANDERSON:

15 Q. Signed Dan Burkley.

16 You wouldn't write that?

17 MR. DAVIS: Object to the form.

18 THE WITNESS: I can't make a comment
19 as to what I would write until I actually go and
20 write that credo.

21 BY MR. ANDERSON:

22 Q. I'm asking you right now, as a
23 34-year employee of an international company that
24 makes products worldwide, some of which will be
25 permanently implanted in human beings, do you

1 believe that part of the credo, if you could write
2 it, should say, we should always put patient safety
3 ahead of corporate profits?

4 MR. DAVIS: Object to the form.

5 THE WITNESS: I would certainly write
6 a statement about the product being safe,
7 efficacious and of high quality, but I would not
8 compare it or put any kind of qualifier in it with
9 respect to profits.

10 BY MR. ANDERSON:

11 Q. If Johnson & Johnson and Ethicon make
12 a profit on a product that is less safe for patients
13 or consumers, or they can make another product that
14 they're not going to make as good a profit on but
15 it's going to be more safe, and they do equally the
16 same thing, which should it use?

17 MR. DAVIS: Object to the form.

18 BY MR. ANDERSON:

19 Q. Which should it make?

20 MR. DAVIS: I'm sorry. Object to the
21 form.

22 THE WITNESS: There are too many
23 variables in that simple comparison that I would
24 have to take into account besides the scenario --
25 besides the details of the scenario that you've

1 given me. And I can't make a judgment call on that.

2 BY MR. ANDERSON:

3 Q. If you look to the third paragraph,
4 "We are responsible to the communities in which we
5 live and work and to the world community as well."

6 Do you see that?

7 A. I do.

8 Q. Do you agree with that as a good rule
9 for Ethicon and its employees?

10 A. Yes.

11 Q. "We must be good citizens -- support
12 good works and charities and bear our fair share of
13 taxes."

14 So if you as an employee of Ethicon
15 and Johnson & Johnson are to be responsible to the
16 communities in which you live and work as well as to
17 the world community, don't you agree that you should
18 have patient safety as your primary concern?

19 A. That paragraph doesn't really address
20 patient safety.

21 Q. I'm asking you this question, though.

22 Based upon, "We are responsible to
23 the communities in which we live and work and to the
24 world community as well." Stop right there.

25 A. It has nothing to do with patient

1 safety.

2 MR. DAVIS: Wait a second. Object to
3 the form.

4 BY MR. ANDERSON:

5 Q. Okay.

6 Your reading of that is what?

7 MR. DAVIS: Object to the form.

8 THE WITNESS: That we have -- the
9 responsibilities that I believe that are meant in
10 that with respect to the community in which we live
11 and work would be such things as being
12 environmentally friendly and being cognizant of
13 environmental laws, being good citizens, support
14 good works and charities, bear our fair share of
15 taxes, in other words, we're responsible for paying
16 our taxes, we contribute to worthy causes and that
17 we're active and do good deeds in the community and
18 encourage civic improvements, better health and
19 education.

20 BY MR. ANDERSON:

21 Q. So other than Johnson & Johnson and
22 Ethicon being a good citizen who is in tune with
23 environmental concerns, taxes, charities and doing
24 good deeds, do you believe that Ethicon and Johnson
25 & Johnson is also responsible to the communities in

1 which you live to make sure that the products that
2 you're making are as safe as possible without regard
3 to corporate profit?

4 MR. DAVIS: Object to the form.

5 THE WITNESS: That might be covered
6 in another section of the credo, but this particular
7 section I believe does not have anything to do with
8 patient safety.

9 BY MR. ANDERSON:

10 Q. I'm not asking about this particular
11 section. You gave me your interpretation of it.

12 A. That's correct, my interpretation,
13 yeah.

14 Q. My question was a follow-up to that.

15 A. Okay.

16 Q. Saying that in addition to the
17 environment and taxes and charities, all of which
18 are good things.

19 A. Right.

20 Q. Do you also believe that being a good
21 citizen of our community, you and your fellow
22 employees at Johnson & Johnson and Ethicon, in order
23 to be good, responsible citizens in the community
24 need to ensure that you put products on the market
25 in which patient safety came before making a dollar?

1 MR. DAVIS: Object to the form.

2 THE WITNESS: I don't believe that
3 consideration is part of this section of the credo,
4 and it's -- you know, that would be addressed in
5 another section of the credo. But as far as being
6 responsible to communities and where we live, it's
7 basically how this business interacts with the
8 community and to, you know, the citizens and to
9 the -- and its responsibilities to government, so...

10 BY MR. ANDERSON:

11 Q. Again, you're trying to interpret it
12 from that section. And I'm not. My question is not
13 is that what this section means.

14 My question is, do you believe as a
15 34-year employee --

16 A. Uh-huh.

17 Q. -- of Johnson & Johnson and Ethicon
18 that you and your fellow employees in designing and
19 manufacturing and selling products --

20 A. Uh-huh.

21 Q. -- to the members of your community,
22 that your credo should say your patient safety comes
23 before us making a dollar?

24 MR. DAVIS: Object to the form.

25 THE WITNESS: I --

1 BY MR. ANDERSON:

2 Q. Would you consider that being a good
3 citizen pursuant to your credo, sir?

4 MR. DAVIS: Object to the form.

5 THE WITNESS: Again, you're asking me
6 to write what the -- to put in what the credo says.
7 There are too many other considerations that have to
8 be weighed before I put in such a statement. And
9 I'm not prepared to go through that. I don't have
10 the means of doing that evaluation or the experience
11 of doing that evaluation, so I'm not comfortable
12 making that statement at this time. So I am
13 confident that the company does keep safety and
14 efficacy in mind with each of its products and that
15 it's of high quality and that these are taken into
16 account when we release our products into the
17 community.

18 BY MR. ANDERSON:

19 Q. So as part of the community, if one
20 of your neighbors comes up and says, I'm considering
21 whether or not to have transvaginal mesh put into me
22 manufactured by your company and I would like to
23 know as a citizen of this community, you, Mr.
24 Burkley, and as a citizen of this community, you as
25 an employee of Johnson & Johnson and Ethicon, did

1 your company put my safety first or your corporate
2 profits first, what are you going to tell that
3 neighbor?

4 MR. DAVIS: Object to the form.

5 THE WITNESS: I can't answer that
6 question.

7 BY MR. ANDERSON:

8 Q. Okay.

9 If you look at the last paragraph,
10 "Our final responsibility is to our stockholders.
11 Business must make a sound profit. We must
12 experiment with new ideas. Research must be carried
13 on, innovative programs developed and mistakes paid
14 for."

15 Do you see that?

16 A. Yes.

17 Q. I'd like to focus on "mistakes paid
18 for."

19 If Ethicon/Johnson & Johnson
20 employees violate their credo and consumers of your
21 products are injured, what should be the penalty to
22 your company?

23 MR. DAVIS: Object to the form.

24 THE WITNESS: That's a pretty
25 complicated question, and I am really not in a

1 position of knowledge or experience to answer that.

2 BY MR. ANDERSON:

3 Q. Do you agree that a company should
4 never needlessly endanger the consumers of its
5 products?

6 MR. DAVIS: Object to the form.

7 BY MR. ANDERSON:

8 Q. Can we agree to that?

9 A. Repeat that, please?

10 Q. That a company should never
11 needlessly endanger the safety and health of
12 consumers of its products?

13 MR. DAVIS: Object to the form.

14 THE WITNESS: Well, I can't account
15 for every type of business there is, but in general
16 I would expect most businesses to do as you've
17 indicated there, to not needlessly put -- I'm sorry,
18 repeat that again?

19 BY MR. ANDERSON:

20 Q. Consumers.

21 A. Consumers.

22 Q. So you would agree with that
23 principle, that companies should not -- strike that.

24 In general, companies should never
25 needlessly endanger the consumers of its products.

1 Right?

2 A. Without knowing the specific nature
3 of the business or what its consumers are, I would
4 say in general, that would be a reasonable
5 expectation. You know, but, again, I don't know the
6 details of any particular company that you're
7 talking about or how that could be extrapolated.

8 Q. Should Johnson & Johnson and Ethicon
9 ever needlessly endanger the consumers of its
10 products?

11 MR. DAVIS: Object to the form.

12 THE WITNESS: Well, I would certainly
13 hope not.

14 BY MR. ANDERSON:

15 Q. Would it be a good principle, even
16 though it may not be the exact words in the credo,
17 would it be a good principle for your company,
18 Johnson & Johnson and Ethicon, to follow, we at
19 Johnson & Johnson and Ethicon should never
20 needlessly endanger the consumers of our products?

21 MR. DAVIS: Object to the form.

22 THE WITNESS: Again, I don't have
23 experience as a business owner or operator. There
24 are a lot more details involved that would need to
25 be considered to make such a conclusion that I don't

1 have at hand, and I just don't feel qualified to
2 make such a strong recommendation as that.

3 BY MR. ANDERSON:

4 Q. You believe that Johnson & Johnson
5 and Ethicon should make products that are as safe as
6 possible for the consumers who buy their products.
7 Correct?

8 MR. DAVIS: Object to the form.

9 THE WITNESS: I guess that would
10 depend on how safe safe can be at the expense of
11 everything else, because you could extrapolate that
12 to an extreme that, you know, may not make it viable
13 as a product or even useful as a product.

14 BY MR. ANDERSON:

15 Q. Some products carry certain risks.
16 Correct?

17 A. Some products do, yes.

18 Q. And some of Johnson & Johnson and
19 Ethicon's products carry risk. Correct?

20 A. Yes.

21 Q. Is it ever okay for Johnson & Johnson
22 to manufacture a product and to sell it to consumers
23 that has needless risk?

24 MR. DAVIS: Object to form.

25 THE WITNESS: Again, that's a

1 scenario that has a number of variables that I'm
2 unaware of, and consequently, I really can't make a
3 qualified answer to that.

4 BY MR. ANDERSON:

5 Q. So just to make sure the jury
6 understands, you, Dan Burkley, as a 34-year employee
7 of Johnson & Johnson/Ethicon don't have an opinion
8 as to whether or not your company should have an
9 internal rule or principle that says we, Johnson &
10 Johnson/Ethicon, should never needlessly endanger
11 the patients who use our products?

12 MR. DAVIS: Object to the form.

13 BY MR. ANDERSON:

14 Q. I just want to make sure I've got
15 that right.

16 A. I don't know -- well, since you're
17 asking my opinion, I don't believe that Johnson &
18 Johnson does that to begin with. So, therefore, I
19 don't see it as a requirement for a credo.

20 Q. There's certainly lots of different
21 employees in your company. Correct?

22 A. Yeah.

23 Q. And different ones have different
24 opinions as to whether or not a product should be
25 put on the market or not. Correct?

1 A. I'm sure they do.

2 Q. Are you saying that one of the
3 guiding principles of Ethicon and Johnson & Johnson
4 should always be, when we're developing this, we
5 should never expose patients to needless danger with
6 our products.

7 Can we agree to that?

8 A. I'm not saying that that's --

9 MR. DAVIS: Wait, wait a second.
10 Object to the form.

11 You can answer.

12 THE WITNESS: I'm not phrasing it the
13 way you did. I don't -- I'm not saying that they
14 have a guideline.

15 BY MR. ANDERSON:

16 Q. Should they?

17 MR. DAVIS: Object to the form.

18 BY MR. ANDERSON:

19 Q. Should Johnson & Johnson and Ethicon
20 have a guideline that says, we should never
21 needlessly endanger the consumers of our products?

22 MR. DAVIS: Object to the form.

23 THE WITNESS: Again, as a -- that
24 would be a business decision. And again, I'm not a
25 business owner or operator and don't have that kind

1 of experience to really explore all the
2 ramifications of adopting such a guideline or not
3 adopting such a guideline.

4 BY MR. ANDERSON:

5 Q. Do you care whether or not women who
6 are implanted permanently with your transvaginal
7 meshes made at Ethicon and Johnson & Johnson are
8 exposed to needless dangers?

9 MR. DAVIS: Object to the form.

10 BY MR. ANDERSON:

11 Q. Do you not care?

12 A. Sure, I care.

13 Q. Well, if you care, don't you believe
14 there should be an internal guiding principle at
15 Johnson & Johnson that says, in making our
16 transvaginal mesh products, we should never
17 needlessly endanger the women in which they're going
18 to be permanently implanted?

19 MR. DAVIS: Object to the form.

20 BY MR. ANDERSON:

21 Q. Should that be a guiding principle?

22 A. I believe that the way that Ethicon
23 designs and develops its products takes the
24 consideration of the safety and health of the
25 patients and -- as well as the quality of the

1 product.

2 Q. And if Johnson & Johnson and Ethicon
3 fail to do that and they manufacture a product that
4 needlessly endangers the consumers of that product,
5 don't you agree that those mistakes or those actions
6 should be paid for?

7 MR. DAVIS: Object to the form.

8 THE WITNESS: Where it indicates
9 mistakes are made, yes, I believe. I believe
10 there's a responsibility to own up to that.

11 BY MR. ANDERSON:

12 Q. And if it's more than a mistake, if a
13 decision is made by Johnson & Johnson/Ethicon to go
14 for corporate profits over patient safety and they
15 needlessly endanger the consumers of its products,
16 they should pay for that. Correct?

17 MR. DAVIS: Object to the form.

18 THE WITNESS: That's a scenario that
19 needs to be defined a lot further than what you've
20 described as a generalization in order for me to
21 make any kind of decision on that.

22 BY MR. ANDERSON:

23 Q. If Johnson & Johnson manufactures a
24 product that is going to be permanently implanted
25 into its consumers, and in manufacturing that they

1 were more concerned with business profits than they
2 were the safety of those patients, thereby
3 needlessly endangering these patients and causing
4 them harm, shouldn't Johnson & Johnson and Ethicon
5 own up to that and compensate those patients?

6 MR. DAVIS: Object to the form.

7 THE WITNESS: Without knowing more
8 details about that, I can't make a comment about
9 that.

10 BY MR. ANDERSON:

11 Q. If a company exposes you to needless
12 harm, should they pay for that?

13 MR. DAVIS: Object to the form.

14 BY MR. ANDERSON:

15 Q. Let me give you that scenario again.

16 If you as a consumer of a product are
17 put in needless harm -- strike that.

18 If you as a consumer of a product are
19 harmed needlessly as a result of a product, do you
20 believe that the manufacturer of that product should
21 compensate you for your harms and losses?

22 MR. DAVIS: Object to the form.

23 THE WITNESS: I'd have to know more
24 about the specific circumstances. I know certainly
25 if it happened to me, I'd need to get as much

1 information as I could about that. If I felt that
2 the company was responsible, sure, I would, you
3 know, try to look for some kind of compensation.

4 BY MR. ANDERSON:

5 Q. For your harms and losses. Correct?

6 MR. DAVIS: Object to the form.

7 THE WITNESS: Again, it depends on
8 the circumstances.

9 BY MR. ANDERSON:

10 Q. If Ethicon and Johnson & Johnson put
11 profits before safety and they created transvaginal
12 mesh products and needlessly endangered thousands of
13 women, if those women suffer harm and injury, should
14 Johnson & Johnson/Ethicon pay for their mistakes --

15 MR. DAVIS: Object to the form.

16 BY MR. ANDERSON:

17 Q. -- pursuant to your credo?

18 MR. DAVIS: Object to the form, I'm
19 sorry.

20 THE WITNESS: Well, the credo is a
21 company-based philosophy.

22 BY MR. ANDERSON:

23 Q. Sure.

24 A. You know, the business will make
25 whatever decisions it's going to make, you know,

1 with keeping the credo in mind. Its
2 responsibilities to the community and, you know, as
3 far as how it operates, it's going to follow the
4 laws of the land as far as that goes, so -- but,
5 again, your -- to make a judgment call on that, I'd
6 need to know a lot more details in order to make
7 that kind of decision.

8 Q. Forgetting the laws of the land for a
9 minute, as a company -- strike that.

10 As a company that makes billions of
11 dollars in profit per year -- strike that.

12 Johnson & Johnson and Ethicon makes
13 billions of dollars in profits per year; is that
14 correct?

15 MR. DAVIS: Object to the form.

16 THE WITNESS: I believe so, yes.

17 BY MR. ANDERSON:

18 Q. So let's work on that premise.

19 A company that makes billions of
20 dollars in profit per year, if they needlessly
21 endanger the consumers of their products and those
22 consumers are injured, no matter what the law is,
23 they should do the right thing and compensate those
24 people for their harms and losses.

25 Would you agree with that, sir?

1 MR. DAVIS: Object to the form.

2 THE WITNESS: It will still depend on
3 the specific nature and circumstances. There's a
4 lot of details that that generalization covers that
5 I'm not privy to and, you know, therefore, I'm just
6 not -- I'm not qualified to really give a comment on
7 that.

8 BY MR. ANDERSON:

9 Q. I'm not asking what you're privy to.
10 I'm saying as someone who's been with this company
11 for 34 years, do you believe it's the right thing to
12 do for Johnson & Johnson and Ethicon, that if they
13 expose women to needless dangers as a result of
14 transvaginal mesh products, and these women are
15 harmed, Johnson & Johnson and Ethicon should do the
16 right thing and step up to compensate these women
17 for their harms and losses? Do you agree with that?

18 MR. DAVIS: Object to the form.

19 THE WITNESS: Again, it's going to
20 depend on the circumstances and just how much fault
21 lays with the company.

22 BY MR. ANDERSON:

23 Q. They made a product in our scenario
24 that needlessly endangered patients.

25 A. Yeah, but in --

1 MR. DAVIS: Wait. If that's a
2 question, I object to the form.

3 MR. ANDERSON: I wasn't through.

4 THE WITNESS: Again, I don't --

5 MR. DAVIS: Oh, I'm sorry.

6 MR. ANDERSON: Quit interrupting me.

7 MR. DAVIS: Yeah. Make sure he gets
8 his question off.

9 THE WITNESS: Okay, I'm sorry.

10 MR. ANDERSON: I sometimes pause. No
11 problem. The tape's almost done, so -- how much
12 time you got?

13 THE VIDEOGRAPHER: Three minutes.

14 MR. ANDERSON: Oh, three minutes.
15 Okay.

16 BY MR. ANDERSON:

17 Q. So do you believe that it is a
18 guiding principle of Johnson & Johnson/Ethicon that
19 if they have needlessly endangered women's very
20 lives with transvaginal mesh products, and these
21 women are injured and harmed, that they should be
22 compensated for those harms and injuries?

23 MR. DAVIS: Object to the form.

24 THE WITNESS: I don't know if that's
25 a guideline.

1 BY MR. ANDERSON:

2 Q. Should it be?

3 MR. DAVIS: Object to the form.

4 THE WITNESS: Again, I'm not in a
5 position to make a business decision as to what
6 guidelines the business should operate under.

7 BY MR. ANDERSON:

8 Q. If a company in the United States
9 manufacturing a product needlessly endangers and
10 harms the consumers of its products, do you believe
11 that it should compensate those individuals for the
12 harms and losses that they received?

13 MR. DAVIS: Object to the form.

14 THE WITNESS: It's going to depend on
15 the details and circumstances of that incident.

16 BY MR. ANDERSON:

17 Q. So as a general principle, you can't
18 agree with that?

19 MR. DAVIS: Object to the form.

20 THE WITNESS: Not without knowing
21 more details.

22 MR. ANDERSON: Okay. Why don't we
23 take a break.

24 THE VIDEOGRAPHER: We're going off
25 the record. The time is 10:45 a.m. This is the end

1 of Tape Number 1.

2 - - -

3 (A recess was taken from 10:45 a.m.
4 to 11:01 a.m.)

5 - - -

6 THE VIDEOGRAPHER: We're back on the
7 record. Here marks the beginning of Volume 1 and
8 Tape Number 2 of the deposition of Daniel Burkley.
9 The time is 11:01 a.m.

10 BY MR. ANDERSON:

11 Q. I show you Plaintiff's Exhibit T-271.

12 - - -

13 (Deposition Exhibit No. T-271, "Our
14 Ethical Code for the Conduct of Research
15 and Development," 1 page, was marked for
16 identification.)

17 - - -

18 BY MR. ANDERSON:

19 Q. I also printed this off from the J&J
20 website. "Our Ethical Code for the Conduct of
21 Research and Development."

22 Have you ever seen this document
23 before?

24 A. I think I've seen it once.

25 Q. When was that?

1 A. Probably about two or three years
2 ago.

3 Q. Under what circumstances, please?

4 A. It was brought to my attention, so I
5 took a look at it briefly.

6 Q. When you read it, did you agree with
7 the principles contained in it?

8 A. Yes, I did.

9 Q. Do you follow the principles
10 contained in it?

11 A. I do.

12 Q. Is one of the purposes of the credo,
13 whether we're talking about the one we just spoke
14 about or this R&D portion of it, is one of the
15 primary purposes of that patient safety?

16 A. Patient safety is certainly a
17 consideration. I don't know if it's paramount.

18 Q. Okay.

19 Under the "Preamble" of this
20 document, Plaintiff's T-271, it says, "Our Ethical
21 Code for the Conduct of Research and Development is
22 intended to complement our credo--"

23 And "our credo" was the document we
24 just looked at, T-270. Correct?

25 A. Yes.

1 Q. -- "by providing more specific
2 standards of conduct and behavior for physicians,
3 clinical research" assistants or "scientists and
4 others who are responsible for medical aspects of
5 research and development."

6 So --

7 And that's talking about physicians,
8 research scientists and others responsible for
9 medical aspects of R&D who are Ethicon and Johnson &
10 Johnson employees. Correct? That's what it's
11 referencing?

12 A. Yeah, clinical research scientists
13 and others who are responsible for medical aspects
14 of research, yes.

15 Q. Who are also employees of Johnson &
16 Johnson and Ethicon. Right?

17 A. Yes, yes. That's correct.

18 Q. You would be contained within that --
19 those set of titles. Correct?

20 A. That I'm not too sure about. I'm not
21 a clinical research scientist, and I'm certainly not
22 responsible for medical aspects.

23 Q. Do you believe that Johnson & Johnson
24 and Ethicon intends for you, Dan Burkley, as an
25 employee, to follow this credo?

1 MR. DAVIS: Object to the form.

2 Ben, I only objected that time
3 because you said "this credo."

4 MR. ANDERSON: That's a good point.

5 BY MR. ANDERSON:

6 Q. So right now we're going to
7 reconcile -- can we call this the R&D credo for
8 purposes of the record? Is that okay for you?

9 A. That's fine.

10 Q. So do you believe that Ethicon
11 intends for all of its employees to follow this more
12 specific standard of conduct for its employees?

13 A. No, considering they have a qualifier
14 in there.

15 Q. So do you believe this applies to
16 you?

17 A. Technically, no.

18 Q. Okay.

19 If you look at the second bullet
20 point, "Our Ethical Code is intended to describe the
21 principles that guide ethical decision-making to
22 ensure the safe use of our products, and the best
23 interests of our patients and their families,
24 doctors, nurses and health care providers."

25 Do you believe that that is a good

1 rule for Johnson & Johnson and Ethicon to have
2 internally, that ethical decisions should be made to
3 ensure safety of its products for patients and their
4 families?

5 A. Yes.

6 Q. Okay.

7 If you look under "Our Ethical Code."

8 "It is our fundamental responsibility
9 to place the well-being of the patient first by
10 appropriately balancing risks and benefits and to
11 ensure the best interests of" physicians -- "of
12 patients and physicians who use our products receive
13 utmost consideration."

14 Do you see that?

15 A. I do.

16 Q. Do you believe that that principle
17 stands for the code of conduct by Ethicon and
18 Johnson & Johnson employees that, in everything that
19 you do, you should put the well-being, the health
20 and safety of patients first?

21 A. In everything we do. That sounds
22 like an absolute statement, which is not included in
23 here, so I'd have to say that that may be an
24 overextrapolation.

25 Q. Do you believe that that is the

1 primary consideration, and that being the
2 well-being, the health and safety of the patients
3 coming first?

4 A. A primary -- yeah. I believe it's a
5 primary consideration, yes.

6 Q. If you look down five bullet points,
7 "It is our responsibility to ensure all
8 Company-based, medically relevant product
9 information is fair and balanced, accurate and
10 comprehensive, to enable well-informed risk-benefit
11 assessments about our products."

12 Do you see that?

13 A. I do.

14 Q. Do you agree with that principle?

15 A. I do agree with that principle.

16 Q. And what is your understanding of
17 what fair and balanced means?

18 MR. DAVIS: Object to the form.

19 BY MR. ANDERSON:

20 Q. In the context of how Johnson &
21 Johnson defines it within its credos?

22 MR. DAVIS: Object to the form.

23 THE WITNESS: I'm not quite sure how
24 to interpret that without a specific example.

25 BY MR. ANDERSON:

1 Q. What's your general understanding of
2 what fair and balanced means, providing fair and
3 balanced information? Doesn't that mean you give
4 the good with the bad?

5 MR. DAVIS: Object to the form.

6 BY MR. ANDERSON:

7 Q. And you're accurate and thorough?

8 MR. DAVIS: Object to the form.

9 THE WITNESS: Well, that you -- you
10 know, that you certainly -- I would interpret that
11 to mean that you consider all the information that's
12 available about it and it be fair in terms of
13 explaining, you know, pros and cons, positives and
14 negatives, you know, different aspects about it.

15 BY MR. ANDERSON:

16 Q. And as that's applied to you as a
17 scientist, do you believe that fair and balanced
18 means that if you undertake a study or an analysis,
19 that you need to provide information that is
20 accurate, comprehensive, fair and balanced?

21 MR. DAVIS: Object to the form.

22 THE WITNESS: Well, I don't normally
23 use the term "fair and balanced" with respect to
24 studies or reports, but we certainly do include the
25 other descriptives that you indicated being

1 accurate, factual and presenting all the data.

2 BY MR. ANDERSON:

3 Q. Well, for instance, let's just -- I'm
4 trying to think of an example.

5 Let's say the FDA were to request
6 information of your company, and you as a scientist
7 were going to provide certain information, and they
8 wanted to know about a potential complication or
9 risk.

10 If you're involved in it as a
11 scientist and you're trying to provide that
12 information to a regulatory body like the FDA, you
13 would want to provide both the positive and the
14 negative, the pros and the cons of your particular
15 research. Correct?

16 MR. DAVIS: Object to the form.

17 THE WITNESS: If they ask for my
18 work, they would get the entire study, which would
19 include all that, whatever information is in there.

20 BY MR. ANDERSON:

21 Q. Do you believe that a regulatory body
22 has the right to assume that Johnson & Johnson and
23 Ethicon will provide the good and the bad
24 information that they have concerning a particular
25 complication or potential problem with one of its

1 products?

2 MR. DAVIS: Object to the form.

3 BY MR. ANDERSON:

4 Q. Is that a good guiding principle?

5 MR. DAVIS: Object to the form.

6 THE WITNESS: Well, your question is
7 putting me in the role of the regulatory body. I
8 don't have regulatory experience. And it would be
9 very speculative of me to try to assume what they
10 would expect and not expect. So I -- it's not -- I
11 don't feel it's an appropriate question to answer.

12 BY MR. ANDERSON:

13 Q. Do you think it's appropriate for a
14 regulatory body like FDA to receive truthful and
15 accurate and thorough information from scientists at
16 Johnson & Johnson and Ethicon?

17 MR. DAVIS: Object to the form.

18 THE WITNESS: I believe that the FDA
19 would expect to receive the information that they
20 asked for.

21 BY MR. ANDERSON:

22 Q. Okay.

23 But if they have a question to ask of
24 your company and you have data, should you provide
25 accurate, truthful and thorough information to that

1 regulatory body?

2 MR. DAVIS: Object to the form.

3 THE WITNESS: They should provide a
4 complete answer to their questions.

5 BY MR. ANDERSON:

6 Q. Should it be truthful and accurate?

7 A. Yes.

8 Q. Okay.

9 Do patients and doctors deserve the
10 same level of respect as a regulatory body in that
11 should patients and doctors who use Johnson &
12 Johnson/Ethicon's products expect that Johnson &
13 Johnson and Ethicon will provide truthful, accurate
14 and full, thorough information about their products
15 to them?

16 MR. DAVIS: Object to the form.

17 THE WITNESS: A customer is going to
18 have different questions and/or concerns than a
19 regulatory body would, so there isn't exactly a
20 parallel between those two; but certainly if an end
21 user had specific questions, you know, the company
22 should attempt to give the end user adequate
23 answers.

24 BY MR. ANDERSON:

25 Q. And by adequate, can we extend that

1 to say that it should be truthful and accurate and
2 thorough information?

3 MR. DAVIS: Object to the form.

4 THE WITNESS: I don't know any --
5 let's see. What am I trying to say?

6 In that particular role, which is not
7 my role, I'm unclear as to what the company's
8 responsibilities would be or what their guidelines
9 should be in terms of dealing specifically with
10 customer requests or requests for additional
11 information, other than what's provided typically in
12 the IFU provided for each product.

13 BY MR. ANDERSON:

14 Q. Okay.

15 Should the IFU contain truthful,
16 accurate and fair and balanced information?

17 A. I believe so, yes.

18 Q. And if you as a scientist at Ethicon
19 are asked to provide scientific data to, for
20 example, a regulatory body, should it be truthful,
21 accurate and thorough information?

22 MR. DAVIS: Object to the form.

23 THE WITNESS: Please repeat that
24 question one more time.

25 BY MR. ANDERSON:

1 Q. Sure.

2 And if you as a scientist at Ethicon
3 are asked to provide scientific data to, for
4 example, a regulatory body, should it be truthful,
5 accurate and thorough information?

6 MR. DAVIS: Object to the form.

7 THE WITNESS: As a scientist, I would
8 certainly provide that information, but as a
9 company, I believe there would be policies that the
10 company would probably need to review that
11 information before it was released.

12 BY MR. ANDERSON:

13 Q. Regulatory bodies who, like the FDA
14 and other organizations around the world that are
15 similar to FDA, one of the primary reasons they
16 exist is to try to ensure patient safety of goods
17 and products that are sold in its country, correct,
18 over which it has regulatory authority?

19 A. Right. That's one of their concerns.
20 I believe that.

21 Q. So if patient safety is a concern of
22 a regulatory authority, would you agree with me that
23 Johnson & Johnson and Ethicon have an obligation to
24 provide truthful and accurate information to
25 regulatory bodies about their products?

1 A. I don't know what their legal
2 obligations are, but from an ethical point of view,
3 yes, I believe they would.

4 Q. Okay.

5 Would you agree that a medical device
6 manufacturer must not put their products on the
7 market without knowing the risks involved --

8 MR. DAVIS: Object to the form.

9 BY MR. ANDERSON:

10 Q. -- by using that product?

11 MR. DAVIS: I'm sorry, object to the
12 form.

13 THE WITNESS: Again, that's a
14 business decision. I'm not in that kind of position
15 as a business owner or operator to really draw upon
16 any experience or knowledge of requirements,
17 obligations, to make those kinds of decisions.

18 BY MR. ANDERSON:

19 Q. Mr. Burkley, as a well educated, very
20 bright principal engineer who's been employed by a
21 multi-billion dollar medical device manufacturer for
22 34 years, do you believe that your company should
23 know the risks involved with its products before
24 they put them on the market and before United States
25 citizens use them?

1 MR. DAVIS: Object to the form.

2 THE WITNESS: The company should be
3 aware of risks associated with the products, yes.

4 BY MR. ANDERSON:

5 Q. Okay, thank you.

6 Do you believe that once problems are
7 identified with regard to products that are already
8 on the market by Johnson & Johnson, that your
9 company should take appropriate steps to identify
10 the problem, analyze the problem and come up with a
11 solution?

12 MR. DAVIS: Object to the form.

13 BY MR. ANDERSON:

14 Q. Let me ask it a different way.

15 Do you feel that your company,
16 Johnson & Johnson and Ethicon, has an obligation to
17 patients and doctors after the product is put on the
18 market to ensure that it is safe while being used?

19 MR. DAVIS: Object to the form.

20 THE WITNESS: The company is
21 certainly concerned about the quality of the
22 products that it sells and is diligent about quality
23 improvement. So consequently, yes, they have
24 concerns over the quality of the product and
25 opportunities to improve quality.

1 BY MR. ANDERSON:

2 Q. In other words, you said a few
3 minutes ago that you believe one of the fundamental
4 principles of the credo and the R&D credo is patient
5 safety.

6 Do you remember that?

7 A. That's a concern. I didn't say it
8 was a guideline.

9 Q. Okay.

10 That's a concern?

11 A. Yes.

12 Q. It's not a fundamental priority?

13 A. It's a primary consideration, but
14 it's not a guideline.

15 Q. So if patient safety is a primary
16 consideration by Ethicon and Johnson & Johnson based
17 in their credos, does that obligation to patient
18 safety stop once the product is marketed?

19 MR. DAVIS: Object to the form.

20 THE WITNESS: No.

21 BY MR. ANDERSON:

22 Q. So Johnson & Johnson and Ethicon,
23 pursuant to their credo, have an obligation to the
24 consumers of its products that after the product is
25 launched, they will continue to look at

1 complications or other risks to patients that may
2 arise after the product is launched.

3 Can we agree to that?

4 MR. DAVIS: Object to the form.

5 THE WITNESS: State that one more
6 time, please?

7 BY MR. ANDERSON:

8 Q. Sure.

9 So Johnson & Johnson and Ethicon,
10 pursuant to their credo, have an obligation to the
11 consumers of its products that after the product is
12 launched, they will continue to look at
13 complications or other risks to patients that may
14 arise after the product is launched?

15 MR. DAVIS: Object to the form.

16 BY MR. ANDERSON:

17 Q. Do you agree to that?

18 A. Well, you're making an extrapolation
19 that refers back to the original credo, whereas we
20 were talking about this R&D credo document
21 previously. And I believe that you're trying to
22 draw one point from one document and apply it to the
23 other.

24 Q. Okay. If that's your impression,
25 it's wrong.

1 A. Okay.

2 Q. So let me see if I can do better.

3 A. Okay.

4 Q. You said that one of the primary
5 considerations of Ethicon and Johnson & Johnson is
6 patient safety. Correct?

7 A. With respect to the R&D --

8 Q. New question. New question.

9 A. Oh, I'm sorry.

10 Q. Okay.

11 Let's put the credo aside for a
12 moment.

13 A. Okay.

14 Q. If that's confusing us, or we can
15 come back to it.

16 But do you believe that one of the
17 primary considerations at Johnson & Johnson and
18 Ethicon should be patient safety?

19 A. It's one of the concerns they should
20 have, yes.

21 Q. And that concern doesn't stop after
22 the product is launched. Correct?

23 A. No. The concern does not stop, no.

24 Q. So in order to ensure a patient's
25 safety after Johnson & Johnson and Ethicon's

1 products are launched, would you agree with me that
2 it should continue to look at new patient
3 complications, new risks associated with its
4 products?

5 MR. DAVIS: Object to the form.

6 THE WITNESS: Well, it should
7 certainly get more information about its products
8 and how they're used.

9 BY MR. ANDERSON:

10 Q. Once problems are identified, should
11 a medical device manufacturer take appropriate steps
12 to do testing and analysis to see if those
13 complications or risks could be eliminated or
14 reduced?

15 MR. DAVIS: Object to the form.

16 THE WITNESS: If a complication has
17 been identified, it should certainly be evaluated
18 and confirmed and then some type of investigation
19 done to determine if it's a quality issue or if
20 there's a way to correct that deficiency or issue.

21 BY MR. ANDERSON:

22 Q. And here's what I'm getting at.

23 Johnson & Johnson/Ethicon has
24 thousands of employees worldwide. Correct?

25 A. Yes.

1 Q. You have scientists, you have
2 doctors, you have engineers, all of the specialties
3 required to research, develop, manufacture and sell
4 medical devices. Correct?

5 A. They do.

6 Q. In fact, Johnson & Johnson and
7 Ethicon are in the best position versus any other
8 company or anyone else in the world to understand
9 its products, to test its products and to analyze
10 any potential complications with its products.

11 Would you agree with that?

12 MR. DAVIS: Object to the form.

13 THE WITNESS: Well, specific to its
14 own products, yes, since it manufactures its
15 products.

16 BY MR. ANDERSON:

17 Q. So if a complication --

18 If a potential complication or a risk
19 with one of Johnson & Johnson and Ethicon's products
20 arises, Johnson & Johnson and Ethicon are in the
21 best position in order to identify that potential
22 complication or patient risk, study it, analyze it
23 and provide some sort of information as to whether
24 they believe it is a true complication or a risk to
25 a patient.

1 Would you agree with that?

2 MR. DAVIS: Object to the form.

3 THE WITNESS: Possibly. There are a
4 number of other scenarios that could exist that
5 might permit other end users or outside research
6 firms to look at that and maybe get other
7 information that Johnson & Johnson or Ethicon, you
8 know, might not have. So, I mean, there are -- you
9 know, there's -- it's conceivable other scenarios
10 could be out there.

11 BY MR. ANDERSON:

12 Q. If Johnson & Johnson and Ethicon are
13 made aware of complications related to its product
14 or potential complications associated with its
15 product, would you agree that your company has a
16 duty and an obligation to reasonably determine the
17 cause of the complications?

18 MR. DAVIS: Object to the form.

19 THE WITNESS: I believe it has a duty
20 to investigate and confirm, and if after it's been
21 confirmed, then to do some investigation or
22 evaluation, you know, about it.

23 BY MR. ANDERSON:

24 Q. Would you agree that Johnson &
25 Johnson and Ethicon must continue to do safety

1 testing, internal studies, to fund external studies,
2 to review all the available new scientific
3 literature that comes out and make any necessary
4 design changes to the product in order to address
5 patient safety issues that may arise during the life
6 of that product?

7 MR. DAVIS: Object to the form.

8 THE WITNESS: Well, that goes to --
9 that's way beyond my area of expertise. And again,
10 it's a business decision. And I'm not really
11 qualified to address a question of such a broad --
12 basically such a broad question.

13 BY MR. ANDERSON:

14 Q. Well, do you believe that your
15 company has an obligation to patients that over the
16 life of that product, if new information is brought
17 to Johnson & Johnson and Ethicon's attention, that
18 there may be safety issues with your product, that
19 Johnson & Johnson should do further testing or fund
20 testing in order to look at that problem?

21 MR. DAVIS: Object to the form.

22 THE WITNESS: Well, Johnson & Johnson
23 certainly has ways of collecting such information,
24 such as product complaints or similar type things,
25 and get as much information about these particular

1 products as possible. And they certainly do
2 investigate those complaints. It's conceivable if
3 it becomes a quality issue, then the company would
4 then do some further investigation about that. But
5 now I'm getting -- beyond that, I don't know exactly
6 what they do or what they would be obligated to do.

7 BY MR. ANDERSON:

8 Q. On the last bullet point of the R&D
9 credo, "It is our responsibility to challenge each
10 other regarding medical and ethical concerns."

11 Do you agree with that?

12 A. As part of the Ethicon R&D code,
13 yeah.

14 Q. Is that something that you regularly
15 do, is challenge your colleagues and have other
16 colleagues challenge one another at Johnson &
17 Johnson and Ethicon regarding medical or ethical
18 concerns with its products?

19 MR. DAVIS: Object to the form.

20 THE WITNESS: Well, considering I'm
21 not a clinician and I'm not a medical doctor, it's
22 kind of rare that I make those kinds of challenges.

23 BY MR. ANDERSON:

24 Q. If you saw an ethical concern at
25 Johnson & Johnson or Ethicon, does the credo require

1 you to challenge those ethical concerns?

2 MR. DAVIS: Object to the form.

3 THE WITNESS: The credo itself does
4 not specifically indicate that, but, I mean, in
5 terms of a principle, certainly here in the ethical
6 code for, you know, R&D, it indicates certainly that
7 for its clinicians and other medical research
8 scientists, you know, that they would bring these
9 things up, so...

10 BY MR. ANDERSON:

11 Q. The last time you and I were together
12 back in October, we had a discussion regarding the
13 2010 publication by Clave, et al. regarding the
14 analysis of 100 explants and the potential
15 degradation of the polypropylene that was seen in
16 those explants that were used for either stress
17 urinary incontinence or pelvic organ prolapse.

18 Do you remember us discussing that?

19 MR. DAVIS: Object to the form.

20 THE WITNESS: I do.

21 BY MR. ANDERSON:

22 Q. And do you recall that you told me
23 that you were asked to be a part of a group of
24 employees at Johnson & Johnson and Ethicon who
25 looked at the Clave study and gave your impressions

1 as to what was contained within that study?

2 A. Yes.

3 Q. Since we last met in October, have
4 there been any further meetings, discussions or
5 communications regarding Ethicon/Johnson & Johnson's
6 analysis of the Clave article?

7 A. No, there have not been.

8 MR. DAVIS: Note my objection to the
9 form of the last question.

10 BY MR. ANDERSON:

11 Q. Were any studies, either internal or
12 external, initiated since we last met in October
13 with regard to addressing the potential for
14 Ethicon's polypropylene meshes to degrade in the
15 human body?

16 MR. DAVIS: Object to the form.

17 THE WITNESS: I'm not aware of any.

18 BY MR. ANDERSON:

19 Q. What were the circumstances under
20 which Ethicon undertook this analysis of the Clave
21 article?

22 MR. DAVIS: Object to the form.

23 BY MR. ANDERSON:

24 Q. In other words, why did you do that?

25 A. I believe that regulatory felt that

1 it would be worthwhile to issue a response to the
2 article.

3 Q. Why did regulatory feel that you
4 should issue a response -- sorry.

5 Why did regulatory at Johnson &
6 Johnson feel that it would be worthwhile to issue a
7 response to the Clave article?

8 MR. DAVIS: Object to the form.

9 BY MR. ANDERSON:

10 Q. Your understanding?

11 MR. DAVIS: Object to the form.

12 THE WITNESS: There were aspects
13 about the study that they felt needed commenting on
14 to offer an alternative viewpoint.

15 BY MR. ANDERSON:

16 Q. To offer an alternative viewpoint to
17 whom? The world at large, through scientific
18 literature, to doctors, to patients? Who are you
19 responding to?

20 MR. DAVIS: Object to the form.

21 THE WITNESS: The same audience of
22 people that would have read the Clave article.

23 BY MR. ANDERSON:

24 Q. Were you aware, Mr. Burkley, that it
25 was actually the United Kingdom regulatory agency

1 MHRA who requested information from Ethicon and
2 Johnson & Johnson regarding its meshes and whether
3 or not they may degrade or contract as was set forth
4 in the Clave article?

5 MR. DAVIS: Object to the form.

6 THE WITNESS: No, I was not aware of
7 that.

8 BY MR. ANDERSON:

9 Q. So no one told you that the reason
10 they were asking you to provide your analysis and
11 your opinion of the Clave article was to respond to
12 a foreign regulatory body who had requested this
13 information from Ethicon and Johnson & Johnson?

14 MR. DAVIS: Object to the form.

15 THE WITNESS: I did not have such
16 information.

17 BY MR. ANDERSON:

18 Q. You said that you had in-person
19 meetings as well as many e-mail exchanges regarding
20 this analysis of the Clave article. That's what you
21 told me at the last deposition.

22 A. Yes.

23 Q. Do you remember that?

24 A. Yes.

25 Q. So none of these meetings and none of

1 those communications, you're telling the jury you
2 had no idea that a foreign regulatory authority had
3 actually asked for Johnson & Johnson's response to
4 the Clave article?

5 A. That's correct. I am not aware of
6 that.

7 MR. ANDERSON: Plaintiff's Exhibit
8 T-272.

9 - - -

10 (Deposition Exhibit No. T-272, E-mail
11 chain, top one dated 01 Mar 2012, Bates
12 stamped ETH.MESH.07226377 through
13 ETH.MESH.07226379, was marked for
14 identification.)

15 - - -

16 MR. ANDERSON: Last four Bates are
17 6377.

18 BY MR. ANDERSON:

19 Q. Have you ever heard of the MHRA?

20 A. No, I'm not familiar with that.

21 Q. If I tell you that the MHRA is
22 similar to the FDA division of pharmaceuticals and
23 medical device regulation, do you have any reason to
24 dispute that with me today?

25 A. I'd probably want a confirmation of

1 it.

2 Q. For purposes of the deposition, I
3 want you to assume with me that the MHRA is a
4 regulatory agency in the UK that regulates the
5 medical devices and other products sold in the UK in
6 order to address patient safety as one of its
7 priorities. Okay?

8 A. Okay.

9 Q. If you look at the second page of
10 this e-mail, you'll see that in the middle of the
11 page, it says "From:
12 Clare.Huntington@mhra.gsi.gov.uk."

13 Do you see that?

14 A. I do.

15 Q. It was sent on January 26, 2012, and
16 the subject was "Polypropylene mesh." Correct?

17 A. Yes.

18 Q. And if you look down below, it says,
19 "Study_of_100_explants.pdf."

20 And we know that the Clave article
21 is -- was a study of 100 explants. Correct?

22 A. Yes.

23 Q. And it is being sent to Mark.

24 "Dear Mark, Please find attached a
25 paper suggesting that Polypropylene used in vaginal

1 meshes is not inert. Please could you provide me
2 with your comments on this issue and also tell me
3 about any testing you have carried out to show that
4 the meshes used do not shrink."

5 Do you see that?

6 A. I do.

7 Q. You will recall that part of the
8 Clave article talked about the degradation of both
9 low weight and heavyweight -- lightweight and
10 heavyweight polypropylene fibers. Correct?

11 A. Yes.

12 Q. It also talked about the meshes can
13 contract or shrink in the human body. Correct?

14 MR. DAVIS: Object to the form.

15 THE WITNESS: I believe so, yes.

16 BY MR. ANDERSON:

17 Q. And it also offered that it was the
18 first study to look at explants of polymer meshes in
19 the pelvic floor to determine whether or not meshes
20 degrade in a woman's body.

21 Do you recall that?

22 MR. DAVIS: Object to the form.

23 THE WITNESS: I believe -- yes, I
24 believe that statement was made by the article, yes.

25 BY MR. ANDERSON:

1 Q. And that their conclusion was that
2 they were not inert and that they actually -- strike
3 that.

4 And the conclusion in the Clave
5 article was that based upon their analysis of these
6 explanted meshes, that polypropylene meshes do in
7 fact degrade and are not inert.

8 Do you recall that?

9 MR. DAVIS: Object to the form.

10 THE WITNESS: I -- yes.

11 BY MR. ANDERSON:

12 Q. So if you look up above that, you see
13 that there is an e-mail sent the next day from
14 Complaints at Ethicon GB, which would be Great
15 Britain. Correct?

16 A. Yes.

17 Q. And it's sent to various individuals,
18 and it says, "Dear Melissa and Cary, See below and
19 attached from the MHRA.

20 "I have also attached my response to
21 Ms. Huntington.

22 "I haven't entered this as a
23 complaint but if you need me to enter anything, just
24 please ask?

25 "Can you provide me with a response?

1 "Many thanks, Marjorie."

2 So what we're seeing here is people
3 within Ethicon, both in Great Britain and the United
4 States, sharing this e-mail from the MHRA and
5 looking for a response. Correct?

6 MR. DAVIS: Object to the form.

7 THE WITNESS: Yes.

8 BY MR. ANDERSON:

9 Q. And if you turn to the next page,
10 three days later another e-mail is sent with the
11 same subject line, and it says, "Dan and Brian," and
12 that's Dan Lamont and Brian Kanerviko, "Please see
13 the e-mail below with a request from MHRA regarding
14 pelvic mesh. Brian, who from your team will take
15 lead on helping with this from an RA" -- that would
16 be regulatory affairs. Correct?

17 A. Yes.

18 Q. -- "perspective?"

19 "Thank you! Melissa."

20 And that's on February 14th.

21 And then if you look up above from
22 Laura Vellucci, there's a jump between February and
23 March here, and we're going to get to some of those
24 e-mails in a minute.

25 But it says, "As per our

1 conversation...I am" sending "the original request
2 from the MHRA to comment on the issue:
3 polypropylene mesh used in vaginal repair may not be
4 inert."

5 Do you see that?

6 A. Yes.

7 Q. And you're copied on this e-mail --
8 oh, you're in the -- you're sent this e-mail as
9 well. Correct?

10 A. Yes, I am.

11 Q. It says, "I am copying Dan and John
12 as you have identified them as resources for the
13 needed information. Sandy has provided a response
14 on our testing to show that meshes used do not
15 shrink."

16 Even though polypropylene itself
17 doesn't shrink, you know, don't you, Mr. Burkley,
18 that there's abundant evidence in -- both within
19 Ethicon as well as in the literature outside of
20 Ethicon that surgical meshes do have wound
21 contraction causing the area of the mesh to shrink
22 or contract. You know that. Correct?

23 MR. DAVIS: Object to the form.

24 THE WITNESS: I'm aware of articles
25 that state that, yes.

1 BY MR. ANDERSON:

2 Q. And that's the --

3 That's known within Ethicon, that
4 polypropylene meshes can shrink from 30 to
5 40 percent of their surface area due to normal wound
6 healing and contraction. You know that. Correct?

7 MR. DAVIS: Object to the form.

8 THE WITNESS: I don't know if they
9 can contract to the extent that you just described,
10 but I've heard of that, that they can contract.

11 BY MR. ANDERSON:

12 Q. So to provide an answer back to a
13 regulatory body in the United Kingdom whose purpose
14 is to try to ensure patient safety, to just say that
15 our testing shows that meshes do not shrink, that's
16 not a fair and balanced response. Would you agree
17 with that?

18 MR. DAVIS: Object to the form.

19 THE WITNESS: I can't comment on
20 that. It depends on how you define "shrink."

21 BY MR. ANDERSON:

22 Q. Well, when a regulatory body is
23 asking the manufacturer for information and that
24 manufacturer has information showing that mesh
25 shrinkage and mesh contraction are words that are

1 used virtually interchangeable -- strike that. Let
2 me ask you.

3 You understand that mesh contraction
4 and mesh shrinkage are terms that are used in common
5 vernacular in your industry somewhat
6 interchangeably. You know that. Correct?

7 MR. DAVIS: Object to the form.

8 THE WITNESS: They could be, but
9 shrink could still have multiple definitions.

10 BY MR. ANDERSON:

11 Q. Was that, the fact that shrink could
12 have multiple definitions, sent back to the MHRA to
13 say what is it that you're asking us, because shrink
14 could have multiple definitions? Was that sent?

15 MR. DAVIS: Object to the form.

16 THE WITNESS: I have no idea what the
17 communication was to the MHRA.

18 BY MR. ANDERSON:

19 Q. We'll go through this and we'll find
20 out whether or not --

21 A. Okay.

22 Q. -- your company just said our meshes
23 don't shrink or can you explain to us what you mean
24 by shrink, because you were -- strike that. New
25 question.

1 You were aware as of March 2012,
2 weren't you, Mr. Burkley, that mesh contraction
3 occurred in polypropylene meshes manufactured by
4 Johnson & Johnson/Ethicon? You were aware of that?

5 MR. DAVIS: Object to the form.

6 THE WITNESS: I have heard of
7 articles stating that. How factual that was, I
8 don't know.

9 BY MR. ANDERSON:

10 Q. And the article -- sorry.

11 A. From an analytical chemist's point of
12 view, shrink could have a different meaning than
13 what's used in a clinical application. So it's not
14 clear which applications the term is being used at.

15 Q. As part of this -- we'll get to your
16 part.

17 You were aware as of March 2012 that
18 Ethicon's own consultants had published in the
19 peer-reviewed literature that there is mesh
20 contraction of all polypropylene meshes somewhere
21 between 30 and 40 percent. You were aware of that
22 at this time, were you not?

23 MR. DAVIS: Object to the form.

24 THE WITNESS: I was made aware of
25 that during the deposition in October.

1 BY MR. ANDERSON:

2 Q. Were you aware of that at this time?

3 A. No.

4 Q. Were you asked to provide information
5 as part of this analytical process in providing a
6 response to the UK regulatory body about
7 contraction? Okay? Were you asked to provide your
8 response regarding whether or not your meshes
9 contract or shrink?

10 MR. DAVIS: Object to the form.

11 THE WITNESS: No, my -- I was asked
12 to comment on the SEM images.

13 BY MR. ANDERSON:

14 Q. So your role was more in the
15 degradation rather than the contraction or
16 shrinkage?

17 A. Well, basically to comment on the SEM
18 images.

19 Q. It says, "It would be great if the
20 information you are collecting and the data that
21 Sandy has provided can be tied together so that we
22 can present a complete picture of our understanding
23 of the properties of polypropylene mesh and its
24 appropriateness for use in vaginal mesh products."

25 "A complete picture of our

1 understanding of the properties of polypropylene
2 mesh," do you see that?

3 A. Yes.

4 Q. If Ethicon was aware in March of 2012
5 that it was in the scientific literature that mesh
6 contraction or mesh shrinkage can occur at 30,
7 40 percent but it tells this regulatory body our
8 meshes do not shrink, that's not presenting a
9 complete picture of Ethicon's understanding of the
10 properties of polypropylene mesh, is it, sir?

11 MR. DAVIS: Object to the form.

12 THE WITNESS: Well, I can't comment
13 on what Sandy means by mesh does not shrink or do
14 not -- the meshes used do not shrink. And I would
15 need -- you know, you would have to ask her
16 viewpoint in terms of what she means by that
17 statement relative to your statement about
18 contractures.

19 BY MR. ANDERSON:

20 Q. If Ethicon and Johnson & Johnson
21 wanted to provide a complete picture of its
22 understanding of the properties of polypropylene
23 mesh with regard to mesh shrinkage, if it was going
24 to follow its credo, it would have provided the
25 literature and the testing of which it was aware

1 showing that there's mesh contraction or mesh
2 shrinkage of up to 30 to 40 percent.

3 Would you agree with that?

4 MR. DAVIS: Object to the form.

5 THE WITNESS: If it had that data,
6 that would certainly be part of the complete
7 picture.

8 BY MR. ANDERSON:

9 Q. Right.

10 And if it had that data and did not
11 provide a complete picture, that's a violation of
12 its own credo. Correct?

13 MR. DAVIS: Object to the form.

14 THE WITNESS: That's a judgment call
15 on the credo, and I'm not in a position to make a
16 judgment call on that.

17 BY MR. ANDERSON:

18 Q. Let's go back to the credo.

19 It says, "It is our" responsible --
20 "responsibility to ensure all Company-based" or
21 "medically relevant product information is fair and
22 balanced, accurate and comprehensive, to enable
23 well-informed risk-benefit assessments about our
24 products."

25 When a regulatory body from the

1 United Kingdom is asking about the mesh shrinkage of
2 your product, in order to follow your own credo at
3 Johnson & Johnson and Ethicon to provide fair,
4 balanced, accurate and comprehensive information and
5 to present a complete picture of the understanding
6 of the properties of polypropylene, you had an
7 obligation and a duty both internally and to this
8 regulatory body to ensure that you made them aware
9 of 30 to 40 percent mesh contraction or mesh
10 shrinkage of your products. Agreed?

11 MR. DAVIS: Object to the form.

12 THE WITNESS: The inquiry is actually
13 made about the article. It's not made about this
14 contracture to 30 or 40 percent.

15 BY MR. ANDERSON:

16 Q. Let's go back to the initial request,
17 Mr. Burkley --

18 A. Yeah.

19 Q. -- from Clare Huntington.

20 A. Okay.

21 Q. She says, "Please could you provide
22 me with your comments on this issue and also tell me
23 about any testing you've carried out to show that
24 the meshes used do not shrink."

25 Do you see that?

1 A. Yes.

2 Q. And if you had testing carried out
3 either internally or externally through consultants,
4 published in the worldwide peer-reviewed literature
5 that said polypropylene meshes shrink from 30 to
6 40 percent, in keeping with your credo and in just
7 doing the right thing, you should have told the MHRA
8 that you're aware of mesh contraction or mesh
9 shrinkage of 30 to 40 percent.

10 Do you agree?

11 MR. DAVIS: Object to the form.

12 THE WITNESS: I can't comment on who
13 generated the data that included the contraction
14 from 30 to 40 percent. I don't know if that's an
15 internal study or an external study. This statement
16 is asking for any testing that you've carried out to
17 show the meshes do not shrink. That would fall
18 under Sandy's area of responsibility, and it
19 indicates that she has provided a response on our
20 testing that show that meshes do not shrink. I
21 don't know how complete or incomplete that is, and I
22 really can't comment any further about it.

23 BY MR. ANDERSON:

24 Q. Well, I'm going to ask you to comment
25 further about it, because it's one thing just to

1 answer the question and only answer the question.
2 It's another to provide full and accurate
3 information, even if it wasn't the exact specific
4 technical question, wouldn't you agree?

5 MR. DAVIS: Object to the form.

6 THE WITNESS: In principle. In
7 principle, I would agree with that.

8 BY MR. ANDERSON:

9 Q. And if as of March of 2012 Ethicon
10 had internal PowerPoints and internal studies
11 showing that they were aware that all of their
12 polypropylene meshes shrink, that information should
13 have been provided to Mrs. Huntington at the MHRA.

14 Would you agree with that?

15 MR. DAVIS: Object to the form.

16 THE WITNESS: I can't comment on
17 that. I personally don't know if such information
18 was available. It's outside my area of expertise
19 and I just can't comment any further about it.

20 BY MR. ANDERSON:

21 Q. Well, if you're in this --

22 They've asked you, you said there was
23 a series of meetings, there was e-mail
24 communications back in March of 2012 about providing
25 the response to the Clave article. Correct?

1 A. Yes, yes.

2 Q. If in the course of those meetings it
3 came up that Ms. Huntington has said that she would
4 like to know if we have any studies about mesh
5 shrinkage, if your company had internal documents
6 showing that they were aware of mesh shrinkage,
7 would you agree with me, sir, that those should have
8 been provided?

9 MR. DAVIS: Object to the form.

10 BY MR. ANDERSON:

11 Q. Or that information should have been
12 provided to this regulatory person?

13 MR. DAVIS: Object to the form.

14 THE WITNESS: I can't make a comment
15 on that. I don't know what information was there.
16 I don't know what information was available. And I
17 don't know how it would all be put together to
18 present this, quote, complete picture.

19 BY MR. ANDERSON:

20 Q. But that is my point, is if the
21 information was available to Johnson & Johnson and
22 Ethicon, when this woman made this response, as part
23 of this team, wouldn't you believe that this should
24 be provided to this woman --

25 MR. DAVIS: Object to the form.

1 BY MR. ANDERSON:

2 Q. -- whose job, at least in part, is
3 ensuring patient safety, women's safety and
4 well-being in the UK?

5 MR. DAVIS: Object to the form.

6 THE WITNESS: Again, that's a
7 business decision that would be made by the
8 regulatory affairs representative.

9 BY MR. ANDERSON:

10 Q. I'm not talking about the business
11 decision. I'm talking about a women's health
12 decision. We discussed a few minutes ago that a
13 regulatory body, part of what they do is try to
14 ensure patient safety.

15 Now that you are aware -- strike
16 that.

17 As part of this team, if you knew
18 that Ethicon had internal documents and was aware of
19 external studies by its own consultants showing mesh
20 contraction, don't you believe that women's health
21 dictated that you provide this information to this
22 regulatory body?

23 MR. DAVIS: Object to the form.

24 THE WITNESS: That information, if
25 it's available, should certainly be consulted and

1 weighed in along with all the other data and
2 information that we have in order to address the
3 request about asking for any other information.

4 BY MR. ANDERSON:

5 Q. Well, how about instead of just
6 consulting the information and weighing the
7 information, why not just turn it over to the
8 regulatory agency? That's my question.

9 MR. DAVIS: Object to the form.

10 THE WITNESS: That's not what was
11 asked.

12 BY MR. ANDERSON:

13 Q. Okay. And that was the point we got
14 to a few minutes ago.

15 And that is, you can either do a
16 technical reading of, well, that's not exactly what
17 she was asking, or you could say, this woman is
18 asking from a regulatory body what we know about our
19 mesh shrinkage, what testing's been done.

20 Don't you believe that women's health
21 is important enough for you guys to look internally
22 to see what documents you had, what studies you had,
23 and to look at the scientific literature and to
24 provide that information to her?

25 MR. DAVIS: Object to the form.

1 THE WITNESS: We were certainly
2 obligated to look at whatever information we had
3 available and offer basically -- as they said here,
4 provide comments on this issue and results of --
5 let's see. And tell me about any testing that's
6 been carried out. So that's what should be
7 addressed.

8 BY MR. ANDERSON:

9 Q. And it was addressed.

10 And instead of providing that
11 information, of which your company, a multi-billion
12 dollar manufacturer of medical devices, and in
13 particular these devices, that's what you were
14 obligated to tell her. Correct?

15 MR. DAVIS: Object to the form.

16 THE WITNESS: I'm sorry, repeat that
17 again, please?

18 BY MR. ANDERSON:

19 Q. Instead of providing that information
20 regarding mesh shrinkage and mesh contraction of
21 which your company was aware, your response simply
22 was our meshes don't shrink. Correct?

23 MR. DAVIS: Object to the form.

24 THE WITNESS: I don't know what the
25 response was. I have -- it indicates here that she

1 has a response to show that meshes used do not
2 shrink. I don't know the details of that report and
3 whether or not it includes any of the information
4 that you've cited -- that you've mentioned earlier,
5 so I'm really not -- that's not my area of expertise
6 and I really can't comment on what type of clinical
7 information was provided.

8 BY MR. ANDERSON:

9 Q. You were asked to be a member of a
10 team that had a response to the Clave article.
11 Correct?

12 A. That is correct.

13 Q. As we've looked at these e-mails now,
14 now you understand that the reason for this response
15 was because of a request by a regulatory body in the
16 UK. Correct?

17 A. I do, yes.

18 Q. And part of the reason that
19 regulatory body exists is to protect patient safety.
20 Correct?

21 A. Yes, that's one of the reasons.

22 Q. And if what they're trying to do is
23 protect patient safety, and in particular women's
24 safety and their health, shouldn't your company
25 provide the information that it has regarding

1 shrinkage and contracture of meshes?

2 MR. DAVIS: Object to the form.

3 THE WITNESS: I don't know the answer
4 to that question. There's a lot of factors involved
5 in terms of providing the information, and I'm
6 not -- I'm only one part of that team. And again, I
7 don't know all the information that was available
8 and I don't know how much of that information was
9 used in the response.

10 BY MR. ANDERSON:

11 Q. Is that okay for Johnson & Johnson
12 and Ethicon, when asked to comment on an article
13 that says that its polypropylene meshes may degrade
14 in a woman's pelvis, is it appropriate not to
15 provide all the information you have on that issue?

16 MR. DAVIS: Object to the form.

17 THE WITNESS: I don't know. All the
18 information would have to be reviewed and evaluated
19 to see how much is applicable to the question.

20 BY MR. ANDERSON:

21 Q. Okay.

22 Well, now that we've talked about
23 this today, do you intend to go back to your
24 colleagues and -- I'm looking at the ethical R&D
25 credo.

1 Do you intend to leave our deposition
2 and challenge your colleagues regarding any ethical
3 concerns they may be if in fact they didn't provide
4 the information that they have regarding mesh
5 shrinkage and contracture to this woman from a
6 regulatory body seeking that information?

7 MR. DAVIS: Object to the form.

8 THE WITNESS: I don't know for a fact
9 they have not reported all the information. I don't
10 know enough details to make a judgment call whether
11 or not an ethical issue has been violated or whether
12 one's even up to be challenged.

13 BY MR. ANDERSON:

14 Q. Are you proud of being a Johnson &
15 Johnson and Ethicon employee?

16 A. Yeah, I am.

17 Q. So if you're proud of being an
18 employee of this company that provides products that
19 are going to be permanently implanted in women,
20 ethically are you going to leave here as a scientist
21 and a proud employee and ask your colleagues whether
22 or not all of the information was provided to this
23 regulatory agency when it was asked?

24 MR. DAVIS: Object to the form.

25 THE WITNESS: Well, I'm aware of

1 polypropylene products, both sutures and meshes,
2 have had at least 40 years clinical experience as
3 being nonabsorbable sutures. And, you know, so I'm
4 pretty comfortable with Prolene as a nonabsorbable
5 material. Again, I don't know the specifics about
6 what data was available and what wasn't available,
7 but I do have confidence in my colleagues, both from
8 the clinical and preclinical and regulatory affairs,
9 that, you know, they're the right people to make --
10 you know, to review that data and determine what
11 should be reported to the MHRA.

12 BY MR. ANDERSON:

13 Q. So you're not going to go say
14 anything after this deposition to your colleagues
15 about whether or not they should provide more
16 information on mesh shrinkage and mesh contracture
17 to this regulatory body, are you?

18 A. No. And I probably shouldn't do that
19 for legal reasons, since there's current trials and
20 I haven't talked to my -- any of my colleagues about
21 any of this.

22 Q. Forget the legal reasons, what about
23 the patient safety reasons. Let's talk about that
24 for a minute.

25 Isn't women's -- new question.

1 Isn't women's health important enough
2 that if you have information that you could provide
3 to a regulatory body of which you're aware regarding
4 degradation or shrinkage of your meshes, that you
5 provide that to the regulatory body?

6 MR. DAVIS: Object to the form.

7 THE WITNESS: That's -- again,
8 that's -- I'm not a -- I'm not in preclinical, I'm
9 not a clinician, that's not my area of expertise.
10 And all I know is that whatever information I do
11 have should be provided to, you know, those experts
12 within my company to use as appropriate for
13 responding to regulatory agencies.

14 BY MR. ANDERSON:

15 Q. You said you had 40 years of
16 experience with Prolene sutures, therefore, you had
17 a certain confidence level. Correct?

18 A. Well, Prolene itself has had 40 years
19 of clinical experience, so I'm pretty confident in
20 the Prolene line of products.

21 Q. Right.

22 And the Clave article had both
23 Prolene and Prolene Soft in it, didn't it?

24 A. It did.

25 Q. So you told us a little while ago in

1 the deposition that in 34 years at the company,
2 you're only aware of one degradation study that was
3 done 25 -- 28 years ago that was in a dog's heart.

4 Do you remember that testimony?

5 A. Yes, I do.

6 Q. So your company hadn't even done any
7 degradation studies at the time Clave came out.
8 Correct?

9 MR. DAVIS: Object to the form.

10 THE WITNESS: Well, it's a
11 nonabsorbable material, and the clinical data that
12 was available supported that.

13 BY MR. ANDERSON:

14 Q. Yes.

15 But now you have an article with 100
16 explants where it shows that polypropylene mesh that
17 had been extracted and excised from women's pelvises
18 showed that there was in fact degradation. Correct?

19 MR. DAVIS: Object to the form.

20 THE WITNESS: I don't know -- well, I
21 don't know for sure if that was degradation.
22 There's certainly some evidence supporting that
23 there may be some surface sites that are showing the
24 initial signs of degradation.

25 BY MR. ANDERSON:

1 Q. And if it's showing the initial signs
2 of degradation that supported their conclusion that
3 polypropylene is not inert, why didn't your company
4 do any degradation studies --

5 MR. DAVIS: Object to the form.

6 BY MR. ANDERSON:

7 Q. -- after that?

8 A. I'm not convinced that polypropylene
9 is not inert.

10 Q. And as a scientist, there's the thing
11 called the scientific method. Correct?

12 A. Sure.

13 Q. You have a theory, and then you work
14 to see if you can prove that theory. Correct?

15 A. Yeah.

16 Q. So if your theory is I'm not
17 convinced that it cracks, where is your proof that
18 it doesn't? What study has Ethicon done regarding
19 explanted mesh from a woman's pelvis where you could
20 actually look at degradation?

21 A. Well, considering that Prolene mesh
22 is made out of Prolene fiber, you could still go
23 back to suture studies, which is why -- you know,
24 and again, there's 40 year -- 40-plus years of
25 history as -- for -- of polypropylene being used as

1 a nonabsorbable suture material.

2 Q. The only one that you're aware of
3 that Ethicon actually did was a seven-year dog study
4 from the heart.

5 So what I'm asking you is, when you
6 were made aware of Clave's study, why didn't Ethicon
7 or Johnson & Johnson -- strike that?

8 Johnson & Johnson/Ethicon did not do
9 any degradation study after Clave came out to either
10 confirm or refute those findings, did it?

11 MR. DAVIS: Object to the form.

12 THE WITNESS: Well, I'm not aware of
13 any degradation studies. That doesn't mean that
14 none were done.

15 BY MR. ANDERSON:

16 Q. When you leave the deposition today,
17 are you going to go ask your colleagues whether or
18 not any degradation studies have been done since
19 your seven-year dog study back in the '80s?

20 MR. DAVIS: Object to the form.

21 THE WITNESS: Not until after the
22 litigation issues have been resolved.

23 BY MR. ANDERSON:

24 Q. Why not?

25 A. Because there are legal implications.

1 Q. What's more important, legal
2 implications or making sure that women don't have
3 degraded polypropylene in their pelvises?

4 MR. DAVIS: Object to the form.

5 BY MR. ANDERSON:

6 Q. That's my question.
7 What's more important, the legal
8 ramifications for your company of asking your
9 colleagues if they've done degradation studies or
10 letting -- or finding out whether or not the
11 polypropylene that are in women's pelvises
12 permanently implanted actually degrade?

13 MR. DAVIS: Object to the form.

14 BY MR. ANDERSON:

15 Q. Which one is more important?

16 A. Well, I'm pretty confident that the
17 polypropylene itself does not degrade to any
18 significant degree, so the risk I believe is
19 minimal.

20 Q. That's not the answer to my question.

21 My question, you said that there's
22 legal implications if you go and ask your colleagues
23 if they've done any degradation studies since the
24 '80s and certainly since this Clave article came out
25 in 2010 and since you were asked to be on a

1 committee or a group of people in 2012 that looked
2 at this degradation issue in response to a foreign
3 regulatory body's request.

4 And so my question is, are you that
5 worried about legal implications that you won't ask
6 your colleagues about this, when in the balance is
7 degraded polypropylene in a woman's pelvis?

8 MR. DAVIS: Object to the form.

9 THE WITNESS: No, but I'm willing to
10 respect the possible legal risks involved, and I'm
11 confident that the people that are involved in those
12 studies, whether they be in the clinical or
13 preclinical area, you know, are certainly going to
14 be asked that information with respect to any
15 investigations from, you know, as part of this
16 litigation. So it's -- I'm sure that information is
17 going to come out if it does exist.

18 BY MR. ANDERSON:

19 Q. What do you mean by that, I'm sure
20 that information is going to come out if it exists?

21 A. Right. As I said before, I don't
22 know if there were degradation studies initiated, to
23 my knowledge.

24 Q. Okay.

25 A. But if I would -- you know, but I'm

1 assuming that if such studies were done, they would
2 have been organized either under preclinical or
3 clinical.

4 Q. And then you see in this exhibit, the
5 last couple of sentences, after it says that we are
6 going to "present a complete picture of our
7 understanding of the properties of polypropylene
8 mesh and its appropriateness for use in vaginal mesh
9 products. At the end, we can add in Piet's comments
10 from a clinical perspective as well. The response
11 will be a work of art!"

12 Would the response be a work of art
13 if it doesn't complete -- if it doesn't give the
14 complete picture?

15 MR. DAVIS: Object to the form.

16 BY MR. ANDERSON:

17 Q. And you know what I mean by this?
18 It's not an appropriate complete picture if you
19 don't provide the information that you have
20 available to you that's relevant to the issues of
21 degradation and shrinkage. That's not much of a
22 work of art, is it, sir?

23 MR. DAVIS: Object to the form.

24 THE WITNESS: I can't comment on
25 that. That's Laura's comment. I don't know what

1 she means by that.

2 BY MR. ANDERSON:

3 Q. Well, then let's take it out of the
4 context of a work of art.

5 It's not a good piece of work by
6 Ethicon and Johnson & Johnson if somebody charged
7 with patient safety in the UK is asking you for
8 information about contraction and shrinkage and you
9 don't provide all the information you have. That's
10 not good work?

11 MR. DAVIS: Object to the form.

12 THE WITNESS: The response may not
13 require every last piece of work.

14 BY MR. ANDERSON:

15 Q. I didn't ask about every last piece
16 of work.

17 A. You said all.

18 Q. Yeah.

19 If you have relevant information to
20 this issue to present the complete picture --

21 A. Right.

22 Q. -- and you have your own internal
23 documents at Johnson & Johnson/Ethicon saying, we
24 are aware of mesh shrinkage and mesh contraction of
25 30 to 50 percent of our meshes, if you don't provide

1 that to the UK, it's not a complete picture and it's
2 certainly not a work of art. Would you agree with
3 that?

4 MR. DAVIS: Object to the form.

5 THE WITNESS: I don't know the value
6 of that information with respect to answering the
7 questions from the MHRA. That would be the
8 responsibility of the preclinical or clinical
9 representatives.

10 BY MR. ANDERSON:

11 Q. Let's just use common sense, like
12 being a scientist and being an employee of a company
13 that you say you're proud to work for.

14 If a regulatory body read this Clave
15 article and they sent a direct request to your
16 company saying can you provide me with any testing
17 that you have on this shrinkage and respond to this
18 article, the right thing to do would be to look and
19 see if you have that information, and if you have
20 it, provide it to them, regarding shrinkage and
21 contraction of your polypropylene meshes. Right?

22 MR. DAVIS: Object to the form.

23 THE WITNESS: It depends on the
24 circumstances and the details of the request.

25 BY MR. ANDERSON:

1 Q. The circumstances and the details are
2 that a regulatory body charged with patient safety,
3 and in this case women's safety, is asking your
4 company for this information about mesh shrinkage
5 and mesh contraction. And you are in a group that
6 is charged with doing that. That's the backdrop.
7 That's the context.

8 So my question in that context is, if
9 someone were to put a stack of documents in front of
10 you that had scientific literature done by your
11 consultants and internal PowerPoints and other
12 documents indicating that people at Johnson &
13 Johnson and Ethicon charged with responsibility for
14 patient safety and safe product design have said
15 that they're aware of 30 to 40 percent contraction
16 and shrinkage, if you're in that room and you had
17 those documents, you, Dan Burkley, would you say,
18 I've seen the response, this is a regulatory body,
19 let's provide those to her? Or would you say,
20 that's a business decision, that's up to you guys, I
21 wash my hands of it, I don't want to be involved in
22 that? Which way would you go?

23 MR. DAVIS: Object to the form.

24 THE WITNESS: I would go and review
25 the data, each piece, see which ones were

1 appropriate for the response. It's possible that
2 there's data that may be inconsequential or not
3 directly related to what the MHRA has requested. So
4 consequently, it wouldn't -- it may not be necessary
5 to include it. But again, I'm not -- you know,
6 this -- that information that you're asking for is
7 either the clinical or preclinical data, and I'm not
8 the one that's appropriate to make a judgment call
9 as to which articles or which data should be
10 included in the response.

11 BY MR. ANDERSON:

12 Q. Well, there was some -- there was
13 certainly nothing that prevented you or your team in
14 providing this response to her, nothing that
15 prevented you from saying, here's our information.
16 This information over here is of what we consider to
17 be limited value, but it may be important to your
18 decision, this we think is of greater value, and let
19 her make the decision as to whether or not that
20 information is important rather than you making the
21 decision as to whether or not it was important, as
22 Ethicon and Johnson & Johnson? Nothing prevented
23 you from doing that?

24 MR. DAVIS: Object to the form.
25 Object to the form.

1 THE WITNESS: Well, it would
2 certainly be -- you know, the company would
3 certainly reserve the right in terms of how it
4 wishes to do that. But if it wants to take that
5 information and you know, review it internally
6 before it releases it, I mean, it certainly has that
7 right to do that.

8 BY MR. ANDERSON:

9 Q. To your knowledge and as you sit here
10 today, this team that you were asked to be a part of
11 in March of 2012 to respond to the Clave article
12 never provided any documents or information
13 concerning mesh shrinkage or mesh contraction other
14 than to say our meshes don't shrink.

15 Is that your understanding as you sit
16 here today?

17 MR. DAVIS: Object to the form.

18 THE WITNESS: I'm not aware of what
19 information the preclinical or clinical
20 representatives provided.

21 BY MR. ANDERSON:

22 Q. Why are you limiting it to
23 preclinical and clinical? I don't understand why
24 you keep going to that.

25 A. Well --

1 Q. You're an engineer, and so I'm asking
2 you as part of the team, as you sit here today -- so
3 let me reask my question.

4 A. Sure.

5 Q. You as an engineer who was invited to
6 be on this team because of your expertise --

7 A. Right. In analytical chemistry and
8 scanning electron microscopy.

9 Q. Right.
10 You're not aware of any information
11 that was provided by this team to the MHRA
12 concerning degradation and shrinkage other than to
13 say our meshes don't shrink. Correct?

14 MR. DAVIS: Object to the form.

15 THE WITNESS: I'm not aware of what
16 information was provided by the clinical or
17 preclinical representatives that would address that.
18 BY MR. ANDERSON:

19 Q. And if Ethicon/Johnson & Johnson had
20 employees and documents within its organization that
21 do believe that their meshes in fact shrink and
22 suffer contraction, do you as a scientist and a
23 43-year employee believe that that information
24 should have been provided to the MHRA in response to
25 this request?

1 MR. DAVIS: Object to the form.

2 THE WITNESS: That depends on the
3 request and the circumstances.

4 BY MR. ANDERSON:

5 Q. Well, we've gone through the request
6 and the circumstances time and again. The request
7 and the circumstances are this. The Clave article
8 came out, the regulatory body in the UK asked your
9 company for any testing they have on shrinking
10 meshes. That's the context. That's the basis under
11 which it was asked. You formed a committee under
12 that basis.

13 A. We did.

14 Q. And my question is, when they were
15 asked the question, what testing do you have and
16 please respond as to whether your meshes shrink,
17 this group, this company, did not provide any data
18 to your knowledge or documents concerning anyone's
19 belief in the company that their meshes shrink or
20 contract?

21 MR. DAVIS: Object to the form.

22 BY MR. ANDERSON:

23 Q. Correct?

24 MR. DAVIS: Object to the form.

25 THE WITNESS: I'm not aware of any.

1 Now, it indicates here that Sandy has provided a
2 response in her testing to show that meshes do not
3 shrink. I don't know the details of that.

4 MR. ANDERSON: Plaintiff's Exhibit
5 T-273.

6 - - -

7 (Deposition Exhibit No. T-273, E-mail
8 chain, top one dated 29 Feb 2012, Bates
9 stamped ETH.MESH.04038180 and
10 ETH.MESH.04038181, was marked for
11 identification.)

12 - - -

13 BY MR. ANDERSON:

14 Q. Last four Bates 8180.

15 An e-mail that will start in the
16 middle of the first page from Dennis Jamiolkowski to
17 you dated February 28, 2012.

18 Do you see this?

19 A. Yes.

20 Q. The subject is "Your Professional
21 Opinion."

22 Do you see that?

23 A. I do.

24 Q. "Daniel, I have a request of you
25 relying on your considerable experience in the field

1 of microscopy, especially SEM, and most of all on
2 the imaging of surgical threads including
3 polypropylene.

4 "I would like you to review the
5 paper," and it lists the title of the Clave article.
6 Correct?

7 A. Yes.

8 Q. And it was attached to that.
9 Correct?

10 A. Yes.

11 Q. And then in all caps, "PLEASE DO NOT
12 COMMUNICATE ANY OPINIONS VIA E-MAIL AS THESE TYPES
13 OF COMMUNICATIONS MAY BE EASILY MISINTERPRETED BY
14 OTHERS."

15 Others like me, like lawyers or a
16 regulatory body? Who are others?

17 MR. DAVIS: Object to the form.

18 THE WITNESS: Basically by anybody
19 who is not a part of the e-mail chain.

20 BY MR. ANDERSON:

21 Q. Well, why don't you just keep people
22 on the part of the e-mail chain who are involved in
23 the group?

24 MR. DAVIS: Object to the form.

25 BY MR. ANDERSON:

1 Q. What's --

2 To your understanding, what was
3 Dennis so worried about, about communication via
4 e-mail?

5 MR. DAVIS: Object to the form.

6 BY MR. ANDERSON:

7 Q. Was it such a highly sensitive topic
8 that you guys didn't want to put much in e-mail and
9 you wanted to keep it more verbal communication?

10 MR. DAVIS: Object to the form.

11 THE WITNESS: He was probably
12 concerned about having a sentence taken out of
13 context or misinterpreted.

14 BY MR. ANDERSON:

15 Q. Or as you've referred to a few times
16 here in the deposition, worried about legal
17 concerns, huh?

18 MR. DAVIS: Object to the form.

19 THE WITNESS: That is a consideration
20 as well.

21 BY MR. ANDERSON:

22 Q. And then at the top there, Dennis
23 sends an e-mail on February 29, 2012, the next day,
24 "Dan Burkley, a Principle Scientist in our
25 Analytical Group with extensive experience in the

1 field of microscopy, has had a chance to review the
2 paper in question. (Please see the e-mail stream
3 below)."

4 So evidently you received it on the
5 28th, reviewed it and had reviewed it by the next
6 day.

7 Is that what this e-mail chains seems
8 to indicate?

9 A. Yes.

10 Q. And is that representative of your
11 recollection or memory as to what happened?

12 A. Yes.

13 Q. Did you get a phone call before you
14 got this e-mail from anyone indicating that they
15 were going to be sending this to you or that there
16 were some issues concerning this that they were
17 going to forward the paper to you, or did it kind of
18 come out of the blue, as you recall?

19 A. No. I probably got a call from
20 Dennis.

21 Q. And what did Dennis say in that phone
22 call?

23 MR. DAVIS: Object to the form.

24 THE WITNESS: I don't recall
25 specifically, but that he wanted my professional

1 opinion.

2 BY MR. ANDERSON:

3 Q. He didn't mention to you that a
4 regulatory body was asking for information
5 concerning this?

6 A. I don't recall that, no.

7 Q. What else do you recall about that
8 initial phone call?

9 A. That he wanted me to review an
10 article.

11 Q. And provide feedback?

12 A. Right.

13 Q. And once you reviewed it, did you
14 provide that feedback to him verbally?

15 A. I did.

16 Q. And what did you tell him?

17 A. I made a comments on the scanning
18 electron microscopy images in that they were very
19 similar to the explants that I had observed from the
20 seven-year dog study and that I believe that the
21 cracking phenomenon was generated due to desiccation
22 of the test article during preparation.

23 Q. Desiccation meaning what?

24 A. It basically gets dried out.

25 Q. Where are those SEMs from your dog

1 study? They're kept in your files or on your
2 computer or in a hard copy?

3 A. Well, the images that were taken
4 would have been on Polaroids, so I believe those
5 Polaroids still exist.

6 Q. And where are those?

7 A. They should be in T106 in a research
8 tower.

9 MR. DAVIS: I'm sorry, I couldn't
10 hear.

11 BY MR. ANDERSON:

12 Q. T106 research tower?

13 A. Right.

14 Q. And where is the research tower?

15 A. That's located at the Somerville
16 campus at Ethicon. It's the tallest building here.

17 Q. And T106, is that a room?

18 A. Yeah. That's a laboratory.

19 Q. Who maintains the laboratory?

20 A. I do.

21 Q. Is that where you go to work every
22 day essentially?

23 A. In general, yeah, yeah.

24 Q. In other words, do you have your desk
25 and your phone and your computer is there?

1 A. No, no, my office is not in there.
2 It used to be, but no longer.

3 Q. Because this is the lab and you just
4 go there for --

5 A. Yeah.

6 Q. And so if I ask you after the
7 deposition to go to the laboratory at T106 and
8 retrieve those images and make copies of them for
9 your counsel, will you agree to do that, please?

10 A. Yes.

11 Q. Yes? Okay.

12 MR. ANDERSON: Counsel, if I could
13 request that once he makes copies of those images,
14 that you provide them to me, would you agree to do
15 that?

16 MR. DAVIS: I'll make note of that
17 request.

18 MR. ANDERSON: Given that they are
19 Polaroids and they've been around for a little
20 while, if the copies aren't very good, we may just
21 want to come look at the originals. Okay?

22 MR. DAVIS: My only hesitancy is I'm
23 not in charge of documents. I'll pass it along to
24 the people in charge, I'll -- you know.

25 MR. ANDERSON: That's all I can ask.

1 You're here representing the company today.

2 MR. DAVIS: I understand.

3 MR. ANDERSON: I've got nobody else
4 to talk to.

5 MR. DAVIS: That's why I say, I'll
6 pass it along. I've got no problem with your
7 request for the production.

8 MR. ANDERSON: Okay. We've got one
9 minute left on the tape. It's probably a good time
10 for a lunch break.

11 MR. DAVIS: Sure.

12 THE VIDEOGRAPHER: Going off the
13 record. The time is 12:23 p.m. This is the end of
14 Tape 2.

15 - - -

16 (A luncheon recess was taken from
17 12:23 p.m. to 1:17 p.m.)

18 - - -

19 THE VIDEOGRAPHER: We are back on the
20 record. Here marks the beginning of Volume Number 1
21 and Tape Number 3 in the deposition of Daniel
22 Burkley. The time is 1:17 p.m.

23 BY MR. ANDERSON:

24 Q. Going back real briefly, those SEMs
25 that you have from the dog study that are over in

1 tower -- in T106 in the research tower, you still
2 have the SEMs of the competitor's meshes as well or
3 the competitors' sutures as well?

4 A. They would be included in there, yes.

5 Q. Did they show cracking as well?

6 A. Some did, some didn't.

7 Q. Was it to the extent that the Prolene
8 suture was cracked?

9 MR. DAVIS: Object to the form.

10 THE WITNESS: Not to the same degree.

11 BY MR. ANDERSON:

12 Q. And your conclusion as to what the
13 cracking was on the Prolene suture was?

14 A. Well, the cracking itself I believe
15 was an artifact from desiccation effect. But that
16 still, the fact that the cracking, whether it's an
17 artifact or not, it would still indicate that that
18 surface area has undergone some type of change.

19 Q. And you didn't do any further studies
20 yourself in order to see what the cause of that type
21 of change was on the surface area. Correct?

22 A. No additional studies, no.

23 Q. And you did no additional studies,
24 you or anyone at Ethicon, to your knowledge, of
25 explants that came from a woman's vagina versus a

1 suture that came from a dog's heart. Correct?

2 A. I'm not aware of any such studies,
3 no.

4 Q. And the Clave study actually looked
5 at explanted polypropylene meshes, including Ethicon
6 and Johnson & Johnson meshes, that actually had been
7 explanted from a woman's vaginal space. Correct?

8 MR. DAVIS: Object to the form.

9 THE WITNESS: Yes, I believe so.

10 BY MR. ANDERSON:

11 Q. So when you go and get those SEMs, I
12 want all the SEMs from the dog study, please, sir.
13 Okay?

14 A. Yes.

15 Q. Do you keep anywhere in your files at
16 the laboratory or otherwise any other SEM
17 photographs or other analytical results from an
18 examination of Ethicon or competitors' polypropylene
19 meshes?

20 A. Well, there would be data on any
21 other analytical testing that was done basically on
22 any of our materials or products that were archived
23 or logged in under a service request number or LIMs
24 number.

25 Q. What about specific to degradation or

1 any surface irregularities of polypropylene mesh of
2 either Ethicon's products or a competitor's
3 products, do you have SEM photos in your lab of
4 those?

5 A. There may be SEM images. SEM is not
6 necessarily routinely done for competitive
7 assessment but may be done on occasion.

8 Q. And those would be contained in the
9 same place?

10 A. Yes, they would.

11 MR. ANDERSON: We'll request those as
12 well, Counsel.

13 MR. DAVIS: Specifically what is
14 that?

15 MR. ANDERSON: SEM or other
16 analytical chemistry photographs or microphotographs
17 of Ethicon's polypropylene fibers or meshes or
18 sutures as well as competitors' that are also kept
19 by Ethicon.

20 BY MR. ANDERSON:

21 Q. So after you determined that the
22 surface cracking on the suture from the dog study
23 was an artifact from desiccation, did you endeavor
24 to develop any sort of analysis that would attempt
25 to look at surface cracking or other surface

1 irregularities in which you could remove or take out
2 of the equation artifacts that may be due to
3 desiccation?

4 In other words, you thought that
5 artifacts from desiccation were what caused these
6 cracks. Did you attempt to develop any sort of
7 scientific method or analysis that would rule out
8 artifact or desiccation from a review of the surface
9 of polypropylene fibers?

10 MR. DAVIS: Object to the form.

11 THE WITNESS: Well, the challenge is
12 to try to take an explanted material and remove any
13 attached tissue, proteins, that are on there so that
14 you can examine the surface. Since SEM is a surface
15 examination technique, if that's not removed, then
16 all you're going to see is a deposit of material on
17 top of the explant. So if you really want to get at
18 the surface, there has to be some type of a sample
19 preparation or treatment plan to remove the tissue
20 and proteins. I recall one experiment where they
21 tried to use a treatment called Soluene, which is
22 supposed to be effective at removing tissue.

23 BY MR. ANDERSON:

24 Q. How do you spell that?

25 A. S-O-L-U-E-N-E.

1 Q. You said they attempted to use it.
2 Who's they?

3 A. That would be either the -- those
4 that were responsible for the implantation and
5 explantation.

6 Q. At Ethicon?

7 A. Yeah. It's the surgery group.

8 Q. So the surgery group attempted to use
9 Soluene to do what?

10 A. To remove the residual tissue and/or
11 proteins on the implants.

12 Q. Did that attempt fail or have any
13 sort of flaws?

14 A. Well, it did remove the surface
15 tissues and proteins, but again, when you're drying
16 the explants, which SEM at that time had to be done
17 under high vacuum, you're going to end up
18 desiccating the sample anyway. And the cracking
19 phenomenon was still observed.

20 Q. I'm not a scientist, so bear with me.

21 But if one were to attempt an
22 analysis of explanted polypropylene fibers and
23 wanted to use a chemical like Soluene or something
24 else in order to remove residual tissue and protein,
25 but they were concerned that that process itself

1 could lead to surface cracking, in order to rule out
2 whether or not the Soluene or some other chemical
3 that's being used to remove that residue, to rule
4 out that it is causing the cracking, you could put
5 that on a pristine sample and then do the analysis.
6 If you don't see the cracking on the pristine sample
7 but you see it on the other, wouldn't that lead one
8 to believe that the cracking may be due to something
9 other than the Soluene?

10 MR. DAVIS: Object to the form.

11 THE WITNESS: Well, that experiment
12 would indicate that the solvent, or the Soluene in
13 this case, does not affect the polypropylene itself.

14 BY MR. ANDERSON:

15 Q. Right.

16 A. It still indicates -- you know, as I
17 said before, the evidence, the fact that you see
18 cracking may be an artifact, but the fact -- whether
19 it's an artifact or not, it still indicates that
20 that surface, something has happened to it.

21 Q. That's right. And that's my point,
22 is that if you wanted to make sure that the surface
23 cracking of an explanted polypropylene was not due
24 to the solvent to remove the tissue and the protein,
25 you could use that solvent on a pristine mesh and if

1 you don't see the same cracking, that would lead the
2 scientists to look into other factors that may have
3 caused the cracking.

4 Can we agree to that?

5 MR. DAVIS: Object to the form.

6 THE WITNESS: No. I would only
7 indicate that the solvent -- that that treatment is
8 not affecting the unimpacted areas of the
9 polypropylene fiber. The impacted area, in other
10 words, the area that's undergone some type of
11 change, that change would not still be completely
12 understood. It's possible that it may not have been
13 cracked in vivo, but the cracking could have been
14 generated during the desiccation process.

15 BY MR. ANDERSON:

16 Q. Well, that's my point. Maybe we're
17 not communicating well.

18 If you take a polypropylene fiber
19 that is pristine, in other words, it has not been
20 implanted, and you dip it in Soluene and you observe
21 it under SEM and you don't see surface cracking --

22 A. Right.

23 Q. -- and you take an explanted mesh
24 and/or fiber and you put it in Soluene and there is
25 surface cracking, that would lead the scientist to

1 at least go down a course of, well, if the Soluene
2 didn't cause it, what did. Correct?

3 A. Right.

4 Q. Okay. That's my point.

5 So if you wanted to determine whether
6 or not, for instance, the suture that came out of
7 the dog heart had surface cracking due to
8 desiccation from the residue --

9 A. From the sample preparation.

10 Q. -- from the sample preparation, you
11 could use the same sample preparation on a pristine
12 fiber. And if you don't see the cracking, that
13 might lead you to believe, ah, it's not artifact due
14 to desiccation, it may be due to something else,
15 let's do some more testing.

16 Can we agree to that?

17 MR. DAVIS: Object to the form.

18 THE WITNESS: It would indicate that
19 there is a surface area that's been affected. How
20 to characterize that effectively is still a
21 challenge. The Soluene is effective in removing the
22 tissue and the proteins, and you do see, you know,
23 an affected surface that's cracking. What's not
24 completely understood is whether the cracking is
25 originally present in the implanted device or

1 whether the cracking was generated during the sample
2 prep. It still represents that that surface -- that
3 something has happened to that surface, but the
4 state of that surface in vivo is still not
5 completely understood.

6 BY MR. ANDERSON:

7 Q. That's right.

8 And when we don't completely
9 understand something that may cause a failure of a
10 particular implantable medical device, one thing we
11 can do is study that. Correct?

12 A. Yes.

13 MR. DAVIS: Object to the form.

14 BY MR. ANDERSON:

15 Q. And to your knowledge, Ethicon never
16 studied that in order to determine as to whether or
17 not this surface cracking was due to preparation
18 versus some in vivo action. Correct?

19 MR. DAVIS: Object to the form.

20 THE WITNESS: Well, work on the
21 explants was done to try to determine if there were
22 better ways to isolate or, excuse me, to separate
23 proteins and/or tissue, so -- and even with the
24 presence of the cracking, you know, some testing was
25 done to try to understand, okay, what is exactly

1 there, you know, regardless of the fact that it is
2 cracked, what does it look like, you know, what kind
3 of characteristics does it have.

4 BY MR. ANDERSON:

5 Q. Well, "some testing was done to try
6 to understand, okay, what is exactly there, you
7 know, regardless of the fact that it is cracked,
8 what does it look like, you know, what kind of
9 characteristics does it have."

10 That doesn't tell me anything. What
11 I'm trying to find out, sir, it's more of a yes or
12 no question. Okay?

13 After you determined that in your
14 opinion this dog suture had cracking that was due to
15 the preparation of the sample versus something else,
16 what did you, Dan Burkley, do or another analytical
17 scientist or someone at Ethicon, in order to do a
18 different study, to say, okay, I want to find out if
19 pristine samples have this kind of cracking after
20 this same preparation so that you could determine
21 whether or not this was actually in vivo degradation
22 or in vivo cracking that was going on versus
23 something due to the sample preparation. That's
24 what I'm talking about. So it's a yes or a no.

25 Were other studies done after that,

1 yes or no?

2 MR. DAVIS: Object to the form.

3 THE WITNESS: Other testing was done
4 on those same explants.

5 BY MR. ANDERSON:

6 Q. Okay.

7 What testing was that? Because I've
8 not seen those documents. I saw the seven-year dog
9 study and the result of that.

10 Is --

11 Was there something done after that
12 seven-year dog study?

13 A. The seven-year dog study would have
14 included information such as molecular weight.
15 There would have been some physical testing as well.

16 Q. What do you mean by some physical
17 testing?

18 A. Like tensile testing.

19 Q. So is it your opinion that if there
20 is surface cracking of a polypropylene fiber, if it
21 still has the same strength it had before going in,
22 that surface cracking is not due to in vivo
23 degradation?

24 A. No, that's not necessarily --
25 that's -- I wouldn't necessarily conclude that, no.

1 Q. Right.

2 Because that seemed to be the
3 hypothesis that you were working under the last time
4 you and I met, and we never could communicate on it,
5 so I wanted to make sure that that wasn't what you
6 were saying. That just because the tensile testing
7 matches from prior to implantation to after
8 explantation, that surface cracking can't be due to
9 degradation in vivo just because they have the same
10 tensile strength?

11 A. No.

12 Q. Is that right?

13 A. No.

14 MR. DAVIS: Object to the form.

15 THE WITNESS: No, that's correct.

16 BY MR. ANDERSON:

17 Q. Okay.

18 A. It only indicates that what is --
19 what areas of the surface that are being affected
20 apparently have no impact on the performance of the
21 suture.

22 Q. The performance of the suture, yes,
23 but you didn't do any further studies to see what
24 might be happening with the performance of the
25 suture vis-à-vis the foreign body reaction and what

1 was happening in the woman's vaginal space with
2 surgical meshes, did you?

3 MR. DAVIS: Object to the form.

4 THE WITNESS: No studies of the
5 latter nature that you had indicated were done, to
6 my knowledge.

7 BY MR. ANDERSON:

8 Q. And if the credo at Johnson & Johnson
9 and Ethicon stands for a proposition that patient
10 safety is a priority, would you agree with me that
11 it's not in keeping with the credo if you don't do
12 the further study to determine whether or not there
13 is in fact surface cracking and degradation of the
14 polypropylene fibers when it's in a woman's vagina?

15 MR. DAVIS: Object to the form.

16 BY MR. ANDERSON:

17 Q. It's not in keeping with the credo if
18 you don't follow that up. Do you agree?

19 MR. DAVIS: Object to the form.

20 THE WITNESS: That's subject to
21 interpretation.

22 BY MR. ANDERSON:

23 Q. Yeah. And you're the guy that is in
24 the seat to interpret today. I apologize, but
25 that's just the nature of the process.

1 And so if you are aware that there's
2 surface cracking, you believe that -- from a suture
3 from a dog's heart that it might be due to
4 desiccation or artifact from the preparation of the
5 sample, shouldn't women who are going to have
6 polypropylene fibers implanted permanently in their
7 vaginas be able to trust that your company would
8 follow up that study to see if in fact these
9 polypropylene fibers were degrading in their
10 pelvises versus it being just some artifact of
11 preparation on an explant?

12 MR. DAVIS: Object to the form.

13 THE WITNESS: Well, the study that
14 was done as part of a competitive assessment had
15 indicated that after seven years, the physical
16 strength and molecular weight of the material was
17 essentially unchanged. So if there's any kind of
18 degradation going on, it's relatively insignificant
19 at that point.

20 BY MR. ANDERSON:

21 Q. That was your conclusion as a result
22 of a suture that -- a suture is 2 or 3 centimeters
23 long. Right?

24 A. It depends on the nature of the
25 explant. Some of the explants were inches long.

1 Q. Okay.

2 So let's use that. Let's say inches
3 long.

4 A. Uh-huh.

5 Q. Shorter than this piece of paper?

6 A. Probably, yes.

7 Q. About like that?

8 A. Possibly, yeah.

9 Q. We're also talking about something
10 that's the size of essentially fishing line, just so
11 the jury has some relevance?

12 A. Right. That's correct.

13 Q. So a strand of fishing line this long
14 that was sutured into a dog's heart, you made a
15 conclusion that the cracking that was in that suture
16 was due to sample preparation and did no further
17 studies to determine whether or not a surgical mesh
18 implanted in women's vaginas would also undergo that
19 same kind of degradation, did you?

20 MR. DAVIS: Object to the form.

21 THE WITNESS: The data obtained
22 indicated that the device did not suffer any
23 significant loss in molecular weight or in its
24 tensile properties. So in terms of its function,
25 the surface degradation or, say, change in the

1 surface, appeared to be limited and insignificant.

2 BY MR. ANDERSON:

3 Q. And this is a few inches of a single
4 fiber. And the mesh that goes into a woman's pelvis
5 is hundreds of yards long. Correct?

6 A. It could be, yes.

7 Q. Right.

8 And you never did a test on that much
9 polypropylene in a woman's vaginal space to look at
10 explanted meshes to see if they actually underwent
11 surface degradation -- surface cracking due to
12 degradation versus surface cracking due to treatment
13 in order to examine it, did you?

14 MR. DAVIS: Object to the form.

15 THE WITNESS: Not to my knowledge,
16 no.

17 BY MR. ANDERSON:

18 Q. But that was done by Clave and his
19 colleagues. Correct?

20 MR. DAVIS: Object to the form.

21 THE WITNESS: Yeah. Investigations
22 of that type were done.

23 BY MR. ANDERSON:

24 Q. Right.

25 And in response to reviewing that,

1 you used a seven-year dog study from 25 years ago
2 with an SEM analysis of one strand of fiber a few
3 inches long, you used the results of those tests to
4 tell a foreign regulatory body, don't worry about
5 the safety of our pelvic floor meshes in terms of
6 degradation because we've got this 25-year-old
7 study.

8 That's what you told them?

9 A. Essentially --

10 MR. DAVIS: Wait. Object to the
11 form.

12 BY MR. ANDERSON:

13 Q. Essentially what?

14 A. Essentially we -- the question was on
15 the material. The material is Prolene or
16 polypropylene. The suture study that was done is on
17 Prolene suture. And the study on the Prolene fiber
18 could be applied, since it's used in a mesh product,
19 you could leverage that type of a study to make a
20 comment on polypropylene mesh.

21 Q. It's not in keeping with Ethicon's
22 credo of putting patient safety as a priority to
23 rely on one 25-year-old dog study with one suture
24 from a cardiac implantation to say to a regulatory
25 agency, our surgical meshes for the pelvic floor

1 don't degrade over the life of the product. That's
2 not in keeping with the credo, is it?

3 MR. DAVIS: Object to the form.

4 THE WITNESS: I would challenge that
5 statement.

6 BY MR. ANDERSON:

7 Q. You said that the Clave study showed
8 the beginnings of degradation. Correct? That's
9 what you said?

10 A. Yeah. There was some surface areas
11 that indicated that some change was going on.

12 Q. Well --

13 A. It's characterized by cracking under
14 SEM, but it's not clear if the cracking truly does
15 exist in vivo. I believe that the cracking is
16 generated as part of the sample prep and the
17 desiccation effect.

18 Q. So you didn't testify earlier that
19 the Clave study indicated the beginnings of
20 degradation of the polypropylene fibers?

21 MR. DAVIS: Object to the form.

22 THE WITNESS: No. I indicated that
23 the cracking was most likely generated as an
24 artifact from the sample preparation.

25 BY MR. ANDERSON:

1 Q. So you came to the same conclusion
2 that you did 25 years prior when you saw a suture
3 and you saw some cracking there and you said, I
4 believe it's the same thing, the Clave team is
5 seeing what we saw 25 years ago, surface cracking
6 due to sample preparation.

7 MR. DAVIS: Object to the form.

8 BY MR. ANDERSON:

9 Q. Yes or no; am I right?

10 A. Yeah. The surface cracking that they
11 illustrated in the SEM looks to be the same as we
12 examined -- as I observed with the seven-year dog
13 study.

14 Q. You didn't do any follow-up testing
15 of your own of surgically explanted meshes from a
16 woman's pelvis in order to come to that conclusion.
17 Correct? Correct?

18 A. No. I did not do any studies on
19 polypropylene mesh used in a woman's pelvis, no.

20 Q. You said that that dog study was done
21 for purposes of competitive comparison. Correct?

22 A. Yes.

23 Q. It wasn't done in order to determine
24 patient safety. Correct?

25 A. To my knowledge, it was done for a

1 competitive assessment.

2 Q. Right.

3 And you told us earlier that you were
4 not made aware that this work that you were doing on
5 the Clave study in March of 2012 was going to a
6 foreign regulatory agency. Correct?

7 A. That's correct. I was not aware of
8 that.

9 Q. Now that you are aware that it was
10 going to a foreign regulatory agency that we've
11 established is there to try to protect patient
12 safety, do you believe that further studies are
13 warranted to look at possible surface degradation of
14 explanted Ethicon polypropylene meshes?

15 MR. DAVIS: Object to the form.

16 THE WITNESS: Based on the data that
17 I have seen, both from the seven-year dog study and
18 the Clave article, I'm still confident that
19 polypropylene mesh or polypropylene sutures as a
20 nonabsorbable product are safe and efficacious.

21 BY MR. ANDERSON:

22 Q. I asked you at your last deposition,
23 I said, were you aware that Ethicon's pathology
24 consultant for the last 30 years, Bern Klosterhalfen
25 from Duren, Germany, analyzed hundreds of explanted

1 mesh samples. And you said you weren't aware of
2 that.

3 Do you remember that testimony?

4 A. That's correct, I was not aware of
5 that.

6 Q. And I asked you if it would have been
7 helpful for you, when you had this meeting in March
8 of 2012, to have seen what he said about the
9 degradation of polypropylene fibers.

10 Do you remember that?

11 A. Yes. That information could have
12 been useful.

13 Q. So after the deposition, did you go
14 and ask your attorney or anyone in the company, did
15 you say, could somebody provide me with what Dr.
16 Klosterhalfen had to say about hundreds of explanted
17 mesh samples when he looked at them?

18 MR. DAVIS: Let me insert an
19 objection.

20 MR. ANDERSON: Okay. Forget the
21 attorney part.

22 MR. DAVIS: Yeah. I instruct you not
23 to answer with respect to communications with the
24 attorney.

25 MR. ANDERSON: Let me clean up the

1 question and you won't even have to object.

2 BY MR. ANDERSON:

3 Q. After that deposition, I assume you
4 went and talked to your colleagues and said, hey,
5 Mr. Anderson said something about Dr. Klosterhalfen
6 having an analysis of explanted mesh samples.

7 A. I had no conversations with anyone.

8 Q. So you didn't go and look that up.
9 Correct?

10 A. No, I did not.

11 Q. Why not?

12 A. For legal implications, I wanted to
13 wait until after this -- these trials and litigation
14 were completed.

15 Q. How in the world -- strike that.

16 What legal implications would there
17 be for you to go and to at least satisfy your own
18 curiosity --

19 MR. DAVIS: Object to the form.

20 BY MR. ANDERSON:

21 Q. -- as to whether or not Dr.
22 Klosterhalfen had seen degradation in explanted
23 mesh?

24 MR. DAVIS: Object to the form.

25 THE WITNESS: I don't know, but I

1 didn't want to find out the hard way.

2 BY MR. ANDERSON:

3 Q. When it comes to the safety of tens
4 of thousands of women regarding whether or not
5 polypropylene is degrading in their pelvis,
6 shouldn't that be a greater concern than whether or
7 not there might be legal implications for you doing
8 this investigation?

9 MR. DAVIS: Object to the form.

10 THE WITNESS: I'm sure it's a great
11 concern, and I'm sure that people from the
12 preclinical and clinical area would be looking into
13 that. I work in an analytical chemistry area.
14 That's outside my area of expertise.

15 BY MR. ANDERSON:

16 Q. Oh. It's not outside your area of
17 expertise, though, because they came to you as an
18 expert in analytical chemistry --

19 A. Right.

20 Q. -- to weigh in on a response to the
21 Clave article.

22 A. Yes.

23 Q. And they wanted your expertise as to
24 whether or not you knew anything about surface
25 cracking or degradation of polypropylene fibers.

1 Correct?

2 A. Well, to comment on the SEM data that
3 they provided.

4 Q. Right.

5 So I asked you at your deposition,
6 would you have liked to have the data from Dr.
7 Klosterhalfen, and you said yes, that would have
8 been good to have. Correct?

9 A. For the discussion of the group that
10 we had --

11 Q. Correct?

12 A. For the discussion of the group that
13 we had.

14 Q. Well, now that you know that this
15 information was actually being provided to a
16 regulatory agency who is concerned with women's
17 safety long term having these implanted in their
18 bodies, don't you believe it would be in keeping
19 with the credo for you or someone else to provide
20 that information of Dr. Klosterhalfen to this
21 regulatory agency?

22 MR. DAVIS: Object to the form.

23 BY MR. ANDERSON:

24 Q. That's a yes or a no.

25 A. I can't -- I'm uncertain what I

1 would -- how I would respond to that.

2 Q. Well, I'm asking you now.

3 MR. DAVIS: And I object to the form.

4 MR. ANDERSON: Fine.

5 THE WITNESS: That's information that
6 the preclinical and clinical experts would have
7 certainly considered in their response.

8 BY MR. ANDERSON:

9 Q. Well, this is talking about your
10 response.

11 You were the expert on the team from
12 analytical chemistry --

13 A. Right. And I was --

14 Q. Just one second.

15 -- to discuss SEM photos. So I'm not
16 talking about preclinical or clinical.

17 A. Right.

18 Q. I'm talking about you, the 34-year
19 employee who they came to to talk about SEM photos
20 of this.

21 A. Uh-huh.

22 Q. You said that it would have been nice
23 to have had Dr. Klosterhalfen's information as part
24 of that discussion.

25 So I'm asking you now, wouldn't it be

1 nice for you to take that information or discuss
2 that in another meeting and decide whether or not
3 you need to amend your response back to this
4 regulatory agency?

5 MR. DAVIS: Object to the form.

6 THE WITNESS: It would be interesting
7 information to have. I don't know if the
8 information would have directly impacted the
9 response or not.

10 BY MR. ANDERSON:

11 Q. Well, you don't know because you
12 haven't looked at it?

13 A. That's correct.

14 MR. DAVIS: Object to the form.

15 - - -

16 (Deposition Exhibit No. T-274, E-mail
17 chain, top one dated 05 Mar 2012, Bates
18 stamped ETH.MESH.04937874 through
19 ETH.MESH.04937876, was marked for
20 identification.)

21 - - -

22 BY MR. ANDERSON:

23 Q. Plaintiff's T-274.

24 If you look at the bottom of this
25 page, the last four digits are 7874. And this is an

1 e-mail from Laura Vellucci again, March 5, 2012.

2 You're copied on that. Do you see that?

3 A. Yes.

4 Q. And it says, "Brian, Piet and Aaron,
5 I would like to send the following e-mail to Clare
6 Huntington in response to her e-mail below. It will
7 include the response prepared by Dennis, Dan and
8 Sandy as an attachment. Please review the e-mail
9 below and attached response. I would be grateful if
10 you could send any comments to me today as I would
11 like to send a reply to Clare on Tuesday or
12 Wednesday.

13 "Sandy/Dennis and Dan -- I added
14 header" and "footer and minor editing (tradename et
15 cetera). Please let me know if you have any issue
16 with my edits."

17 Then there's an e-mail to Ms.
18 Huntington, saying, "I shared your e-mail regarding
19 the inert nature of polypropylene mesh used in
20 vaginal mesh products with Ethicon scientists who
21 have expertise in analytical chemistry" -- that
22 would be you. Correct?

23 A. Yes.

24 Q. -- "mesh technology and material
25 biocompatibility. They have provided a brief

1 summary of some of the testing performed that
2 demonstrates the biocompatibility of polypropylene
3 material and its inert properties."

4 Do you see that?

5 A. Yes.

6 MR. DAVIS: Object to the form.

7 BY MR. ANDERSON:

8 Q. Do you remember now receiving --

9 And then if you look on the second
10 page, which would be 7875, we do see in fact at the
11 end of this e-mail string in which she had -- Laura
12 Vellucci had said, I'm sending the following e-mail
13 below to Clare Huntington. And then that's the one
14 that we read just a few minutes ago.

15 Do you see that? "Dear Mark," at the
16 very bottom, and then it carries over to the next
17 page? Do you see that?

18 A. Which section?

19 Q. The very bottom of the document that
20 ends in 7875.

21 A. Okay.

22 Q. "Dear Mark," and then on the next
23 page, this was Clare Huntington at MHRA.

24 A. Yes.

25 Q. So does this refresh your

1 recollection that you did in fact receive an e-mail
2 from the team telling you that Clare Huntington at
3 MHRA was requesting this information of your group?

4 A. Yes. I -- yes. I was part of this
5 e-mail string that includes that information, yes.

6 Q. So you were in fact made aware that
7 the MHRA had sent a request to your company and that
8 the information you'd be providing would be going to
9 a regulatory body in the UK. Correct?

10 MR. DAVIS: Object to the form.

11 THE WITNESS: No. I didn't recognize
12 what the MHRA was at that time, no.

13 BY MR. ANDERSON:

14 Q. Did you ask anybody when you received
15 this e-mail, who is Clare Huntington and what's the
16 MHRA?

17 A. No.

18 Q. In the meetings that you were at, no
19 one discussed the fact that Clare Huntington was
20 with a governmental regulatory body in the UK and
21 that's why you guys were meeting in the first place,
22 to conduct this response?

23 MR. DAVIS: Object to the form.

24 THE WITNESS: I'm not aware of that
25 being specifically discussed, no.

1 BY MR. ANDERSON:

2 Q. I show you Plaintiff's Exhibit T-275,
3 which ends with 2397.

4 - - -

5 (Deposition Exhibit No. T-275,
6 Response to e-mail from C. Huntington,
7 March 6, 2012, Bates stamped
8 ETH.MESH.07212397 and ETH.MESH.07212398,
9 was marked for identification.)

10 - - -

11 BY MR. ANDERSON:

12 Q. This document has at the top,
13 "Response to e-mail from Clare Huntington," up in
14 those brackets at the very, very top. Do you see
15 that?

16 A. Yeah.

17 Q. It says, "Response to e-mail from
18 Clare Huntington." Do you see that?

19 A. Yes.

20 Q. And then you see just below that in
21 bold type, "Response to e-mail from Clare Huntington
22 26 January 2012...with attached publication."

23 Do you see that?

24 A. Yes.

25 Q. And then the second page has a space

1 for you to -- for your signature line. Correct?

2 A. That's correct.

3 Q. And ultimately, you signed this
4 document. Correct?

5 A. I did.

6 Q. And when you signed that and you saw
7 Clare Huntington in two different places, did it
8 pique your curiosity as who in the world Clare
9 Huntington was?

10 A. Well, she was the contact that Laura
11 Vellucci wanted to respond to.

12 Q. Right.

13 And did you ask who in the world
14 Clare Huntington was, what organization she was
15 with?

16 MR. DAVIS: Object to the form.

17 THE WITNESS: No, I did not.

18 BY MR. ANDERSON:

19 Q. Do you see in the second paragraph
20 beginning, "The safety and inertness of the fiber"?

21 A. Yes.

22 Q. The second sentence, "In compliance
23 with regulatory mandate, ETHICON has established a
24 complaint reporting system: the Worldwide Customer
25 Quality system. With PROLENE suture, there have

1 been no observations of fiber degradation in
2 complaints received and/or products returned."

3 Do you see that?

4 A. Yes.

5 Q. That wasn't entirely true, was it?

6 MR. DAVIS: Object to the form.

7 BY MR. ANDERSON:

8 Q. You did have in fact have four
9 examples of mesh that had been claimed to be
10 degraded, you just didn't have enough in your file
11 to confirm whether or not it was true; isn't that
12 right?

13 MR. DAVIS: Object to the form.

14 THE WITNESS: I don't recall.

15 BY MR. ANDERSON:

16 Q. Then you see down on the final
17 paragraph there on that page, you see, "In an
18 infected field and/or a site of chronic
19 inflammation, it is not unexpected that there will
20 be an increase in free radicals and other reactive
21 oxygen species. Polymers may be subject to surface
22 degradation by these reactive species, the impact of
23 which has not been clinically assessed."

24 Do you see that?

25 A. Yes.

1 Q. So in fact, you're saying in this
2 response to the UK federal regulatory authority that
3 polymers may be subject to surface degradation due
4 to these oxygen species and free radicals, but the
5 impact has not been clinically assessed. Right?

6 MR. DAVIS: Object to the form.

7 THE WITNESS: Yes, that's essentially
8 what it says.

9 BY MR. ANDERSON:

10 Q. If in fact polymers like the
11 polypropylene in Ethicon and J&J's surgical meshes
12 for the pelvic floor are degrading due to free
13 radicals, other reactive oxygen species or some
14 other in vivo action, it would be in keeping with
15 your credo of putting patient safety first to
16 actually do a study to determine whether or not this
17 occurs?

18 MR. DAVIS: Object to the form.

19 BY MR. ANDERSON:

20 Q. Do you agree to that?

21 MR. DAVIS: Object to the form.

22 BY MR. ANDERSON:

23 Q. That's a yes or no question.

24 Do you agree to that?

25 A. I do not -- I'm sorry, rephrase that.

1 Q. I'll just repeat the question.

2 A. Yeah, repeat it. Yeah.

3 Q. If in fact the polymers, like the
4 poly -- dadgummit. Too fast.

5 MR. ANDERSON: Now you have to do it.

6 - - -

7 (The court reporter read the
8 pertinent part of the record.)

9 - - -

10 MR. DAVIS: Object to the form.

11 BY MR. ANDERSON:

12 Q. Yes or no?

13 A. No, I don't agree with that
14 conclusion. The reason I don't agree with that
15 conclusion is that the extent of the degradation is
16 not known, or in the instances where we've seen it,
17 it's very limited or insignificant.

18 Q. Well, the extent is not known because
19 you haven't done the studies. You haven't looked
20 at -- in Ethicon, you haven't looked at explanted
21 mesh from women's pelvises.

22 MR. DAVIS: Object to the form.

23 BY MR. ANDERSON:

24 Q. You told the jury that already.

25 A. No, but we --

1 MR. DAVIS: Wait. Wait a second.

2 Object to the form.

3 THE WITNESS: No, but we've looked at
4 explanted sutures.

5 BY MR. ANDERSON:

6 Q. 25 years ago in a dog study, one
7 suture from the cardiac?

8 A. Seven years in a dog, 25 years ago
9 should be equivalent to seven years in a dog now.

10 Q. So at the time, though, you didn't
11 know whether or not it was due to some sort of
12 desiccation due to the cleaning. That's my whole
13 point is you've never done a study to look at
14 explanted pelvic floor meshes in order to determine
15 whether or not there is surface degradation due to
16 reactive oxygen species, have you?

17 MR. DAVIS: Object to the form.

18 BY MR. ANDERSON:

19 Q. That's my question.

20 A. No, I'm not aware of any additional
21 studies beyond the dog study that investigates that
22 specifically.

23 Q. And my point is, a multibillion
24 dollar company like Johnson & Johnson, with all its
25 resources, if it wanted to keep with its credo of

1 putting patient safety first, and in this case,
2 women's safety and health for the life of their
3 pelvis, you should have done that study to either
4 rule out or confirm that some in vivo action was
5 causing surface degradation of the polypropylene in
6 their body. True?

7 A. I'd have --

8 MR. DAVIS: Wait a second. Wait a
9 second.

10 Okay. Then I object to the form.

11 THE WITNESS: I'd have to defer to
12 the clinical and preclinical experts who would have
13 access to that -- to far more data than I do to make
14 that type of determination.

15 BY MR. ANDERSON:

16 Q. With all due respect, you can't have
17 it both ways is my position. You can't have it both
18 ways. You can't tell us a minute ago that based
19 upon our seven-year dog study of a suture in the
20 heart it didn't have any clinical implications in
21 patient safety, and then when I say, wouldn't a
22 better study, and if you're really putting patient
23 safety first, be to look at explanted meshes, and
24 then you defer that to clinical. You can't have it
25 both ways. Which way is it?

1 MR. DAVIS: I object to the form.

2 THE WITNESS: The comments I made
3 were concerned about the SEM information, SEM data
4 and the phenomenon of the surface cracking, whether
5 that was an artifact or whether, you know, it truly
6 does exist in the in vivo state, which is not --
7 which I am indicating -- which I have indicated it's
8 my position that it's an artifact generated during
9 sample prep.

10 Now, I do admit that the fact that
11 you see the cracking, whether it's an artifact or
12 not, does indicate that that surface that it's
13 observed on, that something has happened to it. All
14 right? Something that's not completely understood.
15 But from the suture study, the overall molecular
16 weight and tensile strength have not been negatively
17 impacted.

18 There's also clinical data on
19 existing Prolene products that show the product to
20 be safe and efficacious. So consequently, if it's a
21 nonabsorbable material, unless there's, again, other
22 information that strongly suggests that there's a
23 degradation concern to be -- you know, to
24 investigate, I believe there's enough information
25 that doesn't warrant a specific degradation study.

1 BY MR. ANDERSON:

2 Q. The only data that you have specific
3 to SEM --

4 A. Yes.

5 Q. -- is your dog study from the '80s in
6 which you concluded that it must be due to sample
7 preparation, and looking at a piece of paper, the
8 Clave study, not the actual SEM photos, a piece of
9 paper, and saying what I see on that piece of paper
10 looks like what I saw on a suture 25 years ago,
11 therefore, no study needed, no problem with the
12 women, we feel confident that our product is safe
13 and efficacious. That's what you're telling this
14 jury?

15 MR. DAVIS: Object to the form.

16 THE WITNESS: That information, along
17 with the other information from the other experts,
18 we, therefore, conclude that our product is still
19 safe and efficacious.

20 BY MR. ANDERSON:

21 Q. What other information from other
22 experts? I mean, it's one thing to say that. It's
23 another -- I need hard facts here.

24 A. It would be Dennis and Sandy.

25 Q. And what did Dennis and Sandy do in

1 terms of looking at whether free radicals and other
2 reactive oxygen species were leading to surface
3 degradation, which may or may not impact women?
4 What did they do?

5 MR. DAVIS: Object to the form.

6 THE WITNESS: You know, they made
7 their comments concerning the safety and inertness
8 of the fibers as demonstrated by 40 years of
9 clinical experience.

10 BY MR. ANDERSON:

11 Q. You certainly don't have 40 years of
12 clinical experience as of 2012 of putting hundreds
13 of yards of polypropylene material in a woman's
14 vagina, do you, sir?

15 MR. DAVIS: Object to the form.

16 BY MR. ANDERSON:

17 Q. Yes or no?

18 A. There's 40-plus years of --

19 Q. I'm sorry, I've got to object. It's
20 a yes or no question. And I'm entitled to that if
21 you can give it. If you say I can't answer your
22 question, that's fine. But it is a yes or no
23 question, and I am entitled to get that.

24 MR. DAVIS: And you're also entitled
25 to explain. But if can be answered yes or no, you

1 know, answer it.

2 MR. ANDERSON: Thank you.

3 THE WITNESS: I would say no with
4 respect to the mesh products, but for the Prolene
5 line of products, there is a 40-plus year history.

6 BY MR. ANDERSON:

7 Q. And in that 40-year plus history, the
8 only time you ever looked at surface degradation of
9 your product was in the '80s with one suture from a
10 dog's heart. Correct?

11 MR. DAVIS: Object to the form.

12 THE WITNESS: That's the only study
13 that I've looked at, yes.

14 BY MR. ANDERSON:

15 Q. So out of this 40 years of clinical
16 experience, you have one piece of data in terms of
17 one test that you did 25 years before this article
18 came out. Correct?

19 MR. DAVIS: Object to the form.

20 BY MR. ANDERSON:

21 Q. Correct?

22 A. Well, it's not just one test, but it
23 would be several tests done during the --

24 Q. During one study?

25 A. Yes, a seven-year study.

1 Q. Henri Clave, one of the authors, was
2 an Ethicon consultant.

3 You or nobody on the team contacted
4 him, did you?

5 MR. DAVIS: Object to the form.

6 THE WITNESS: I am not aware if
7 anybody on the team contacted him.

8 BY MR. ANDERSON:

9 Q. You never saw the actual SEM photos
10 that are contained in the article, did you?

11 MR. DAVIS: Object to the form.

12 THE WITNESS: I only saw what was
13 reprinted in the article.

14 BY MR. ANDERSON:

15 Q. Did you provide this information to
16 the team that's in the beginning of the final
17 paragraph of this page, "In an infected field and/or
18 a site of chronic inflammation, it is not unexpected
19 that there will be an increase in free radicals and
20 other reactive oxygen species," and then the next
21 sentence, "Polymers may be subject to surface
22 degradation by these reactive species, the impact of
23 which has not been clinically assessed"? Did you
24 provide that information?

25 MR. DAVIS: Object to the form.

1 THE WITNESS: I was -- I participated
2 in the discussion, but I believe Dennis brought that
3 up.

4 BY MR. ANDERSON:

5 Q. And what did Dennis do in terms of
6 studies that he looked at or actual testing by your
7 company to come to those conclusions that were
8 ultimately sent to this foreign regulatory agency?
9 Please tell the jury.

10 A. Well, that would have been a
11 discussion, again, between Sandy and Dennis and I
12 about the types of foreign body reactions that can
13 occur and the different mechanisms that are used on
14 the cellular and microcellular level during those
15 reactions.

16 Q. Okay.

17 So my question is, what did Dennis,
18 and now you've expanded it to Dennis and Sandy and
19 me.

20 A. Right.

21 Q. What did you do in terms of studies
22 that looked at actual testing by your company to
23 come to those conclusions that were ultimately sent
24 to this foreign regulatory agency? Your answer
25 said, there would have been a discussion about this.

1 Okay. That's a discussion.

2 A. Yes.

3 Q. My question is, what testing did you
4 look at or perform? What literature was used in
5 support of this, to support these statements that
6 you're making to this regulatory body? That's what
7 I want to know.

8 MR. DAVIS: Object to the form.

9 THE WITNESS: I did not conduct any
10 specific tests, and I don't recall citing any
11 specific literature.

12 BY MR. ANDERSON:

13 Q. So if we take those statements right
14 there that were made after a discussion --

15 A. Yes.

16 Q. -- and not after any literature
17 search or testing, as you've just testified, if an
18 infected field -- the more bacteria in an infected
19 or contaminated field and the greater the chronic
20 inflammation, then the greater the chance of surface
21 degradation due to these oxidative species, would
22 you agree with that? In other words, the more
23 infection, the more chronic inflammation, the
24 greater the risk of degradation. Correct?

25 MR. DAVIS: Object to the form.

1 THE WITNESS: Yes, I agree with that
2 concept.

3 BY MR. ANDERSON:

4 Q. Okay.

5 And your suture study that you did in
6 a dog heart, that was not in a contaminated field in
7 the way that surgical meshes in a woman's vagina
8 are. Correct?

9 MR. DAVIS: Object to the form.

10 THE WITNESS: No, it was not done in
11 a contaminated field.

12 BY MR. ANDERSON:

13 Q. In fact, a woman's vagina has all
14 kinds of bacteria, strep A, candida, gram-negative,
15 a lot of bacteria in a clean contaminated field that
16 simply doesn't exist in a dog's heart. You agree
17 with that. Right?

18 MR. DAVIS: Object to the form.

19 THE WITNESS: That sounds plausible.
20 I don't recall during the dog study whether there
21 were any infected sites or not.

22 BY MR. ANDERSON:

23 Q. So if you want to compare apples to
24 apples instead of apples to oranges, you wouldn't
25 use a suture from a noncontaminated field to compare

1 to hundreds of yards of suture material in a clean
2 contaminated field of a woman's vagina?

3 MR. DAVIS: Object to the form.

4 BY MR. ANDERSON:

5 Q. Yes or no?

6 MR. DAVIS: Object to the form.

7 THE WITNESS: That depends if you're
8 trying to compare different types of infection
9 versus -- well, from an infection point of view, I
10 would agree with that comparison. But in each of
11 these instances, even a foreign body reaction can be
12 chronic inflammation. And even in those
13 circumstances, it's not unexpected that you could
14 have free radicals and other reactive oxygen
15 species.

16 BY MR. ANDERSON:

17 Q. Well, my question is, the greater the
18 chronic inflammatory response, so if you have a
19 severe inflammatory response and you have mesh that
20 is implanted into a bacterial field, it increases
21 the risk of degradation of the polypropylene. True?

22 MR. DAVIS: Object to the form.

23 THE WITNESS: It could increase the
24 risk.

25 BY MR. ANDERSON:

1 Q. Sure.

2 And your suture material in a dog's
3 heart did not have the same bacterial field or
4 chronic inflammatory response that surgical mesh in
5 a woman's pelvis would. Agree?

6 A. It probably would not.

7 Q. So you are comparing apples to
8 oranges in common vernacular when you're comparing a
9 suture from a dog heart to surgical mesh in a
10 woman's pelvis vis-à-vis infection and chronic
11 inflammation. True?

12 MR. DAVIS: Object to the form.

13 THE WITNESS: No, I disagree with
14 that statement. They're all examples of infection
15 or chronic inflammation.

16 BY MR. ANDERSON:

17 Q. Yes, but the --

18 We just established that there are a
19 lot more bacteria in the contaminated field of a
20 woman's vaginal space than there was one suture in a
21 dog's heart. Correct?

22 MR. DAVIS: Object to the form.

23 BY MR. ANDERSON:

24 Q. We established that, yes or no?

25 A. There would be more inflammation,

1 yes, relatively more inflammation. Correct.

2 Q. And infection?

3 A. And infection.

4 Q. And the more infection and the more
5 inflammation, as we've just established, the greater
6 likelihood of degradation?

7 MR. DAVIS: Object to the form.

8 THE WITNESS: The greater likelihood.

9 BY MR. ANDERSON:

10 Q. Right.

11 A. But not necessarily guaranteed.

12 Q. Right.

13 And so the way we find that out as
14 scientists is what? We study. Correct?

15 A. You can.

16 Q. But you didn't. You didn't.

17 Correct?

18 MR. DAVIS: Object to the form.

19 THE WITNESS: We didn't do that type
20 of comparison study, no. But they're -- like I
21 said, they're all examples of infected fields or
22 chronic infection.

23 BY MR. ANDERSON:

24 Q. In fact, infection and chronic
25 inflammation were two of the potential causes listed

1 by the Clave authors in their study as to what was
2 causing the degradation of the polypropylene meshes
3 that were explanted from women's pelvises in their
4 study. Correct?

5 MR. DAVIS: Object to the form.

6 THE WITNESS: Possibly, yeah.

7 BY MR. ANDERSON:

8 Q. Not possibly, it either was or it
9 wasn't.

10 So my question is, those were two of
11 the potential causes that were listed by the Clave
12 authors in their study as to what was causing the
13 surface degradation of the polypropylene in their
14 study. True?

15 MR. DAVIS: Object to the form.

16 THE WITNESS: I'd have to review the
17 article to be sure.

18 BY MR. ANDERSON:

19 Q. Okay. We'll look at that in a minute
20 then.

21 I want to show you Plaintiff's
22 Exhibit T-276.

23 - - -

24 (Deposition Exhibit No. T-276, Memo
25 dated March 12, 2012, Bates stamped

1 ETH.MESH.07205369 and ETH.MESH.07205370,
2 was marked for identification.)

3 - - -

4 BY MR. ANDERSON:

5 Q. 5369.

6 Now, the last exhibit we looked at,
7 T-275, was the unsigned version of this document.
8 Correct?

9 A. Yes.

10 Q. And if you turn to page 2 of this
11 T-276, it is the signed version. Correct?

12 A. Yes.

13 Q. And if you go down and we take the
14 last document and put it up on the left, first page.
15 Okay. If you can reverse those and highlight the
16 last paragraph on both.

17 If you look at your document there
18 and you compare it to the one that you just had
19 before you?

20 A. Yes.

21 Q. Do you want to pull that one out,
22 too, for me, please?

23 In the final signed version, if you
24 look at the last paragraph, I don't see the
25 language, maybe I'm just missing it and you can help

1 me.

2 Who decided -- let me strike that.

3 Let me go back.

4 Who made the final decision as to
5 what the wording would be in this response?

6 MR. DAVIS: Object to the form.

7 BY MR. ANDERSON:

8 Q. And by who, it could be a group
9 decision as far as I know, but which person or
10 persons at Ethicon were responsible for the final
11 language that was going to be sent to Clare
12 Huntington of the UK regulatory agency, MHRA?

13 A. Well, the document would have been --
14 would have had Dennis and Sandy and myself
15 contributing towards the document. I don't recall
16 who edited the final version.

17 Q. I haven't seen anywhere in either
18 version where your team told this person at MHRA, we
19 have never done a study at Ethicon in these 40-plus
20 years where we actually looked at explanted vaginal
21 meshes and compared them to pristine meshes in order
22 to determine whether or not we have found surface
23 degradation or similar surface anomalies. You
24 didn't tell her that, did you?

25 MR. DAVIS: Object to the form.

1 THE WITNESS: Not that specific
2 statement, no.

3 BY MR. ANDERSON:

4 Q. And you didn't tell her that we have
5 one of the top, if not the top, pathologists,
6 histopathologists in the world on surgical meshes
7 who has sent us data regarding his view on the
8 degradation of explanted vaginal meshes, did you?

9 MR. DAVIS: Object to the form.

10 THE WITNESS: Not specifically stated
11 in this document, no.

12 BY MR. ANDERSON:

13 Q. Not even generally stated in this
14 document. Correct?

15 A. Correct.

16 Q. As this group was meeting to
17 determine what kind of response would be given based
18 upon the Clave article, did anyone offer the
19 suggestion that perhaps we should reach out to our
20 top pathologist who's been looking at our meshes for
21 30 years and ask him his opinion on the degradation
22 of surgically implanted meshes into a woman's
23 pelvis?

24 MR. DAVIS: Object to the form.

25 THE WITNESS: I'm not aware of such a

1 discussion.

2 BY MR. ANDERSON:

3 Q. Don't you think that in order to be
4 in compliance with your internal credo, also just
5 good science, it would have made sense to have
6 reached out to your pathologist who's looked at your
7 explanted meshes and the explanted meshes of other
8 manufacturers in order to determine whether or not
9 you needed to give a thorough response of whether or
10 not you've seen surface degradation of your
11 polypropylene?

12 MR. DAVIS: Object to the form.

13 THE WITNESS: I would leave that up
14 to the opinion of our toxicologists and pathologists
15 that were at the Somerville site.

16 BY MR. ANDERSON:

17 Q. And please tell me which
18 toxicologists and pathologists were involved in
19 these e-mail strings?

20 A. Well, Sandy Savidge would be the
21 preclinical representative, so ultimately it would
22 be her call.

23 Q. Well, preclinical doesn't necessarily
24 look at once a product has been put in by a
25 clinician and it's been explanted, she's not

1 necessarily involved with that aspect of the
2 business. Correct?

3 A. No.

4 Q. I mean, that's correct. Correct?

5 A. Right. She's not typically involved
6 with that aspect, that's correct.

7 Q. Right.

8 So tell me who on the team is someone
9 who would have had access to that information.

10 Strike that.

11 You said a minute ago that decision
12 would have been made by someone else in preclinical
13 or clinical?

14 A. Yes.

15 Q. So what I'm asking is, who here would
16 actually be involved in the -- in working with
17 pathologists and histopathologists for explanted
18 material for humans?

19 MR. DAVIS: Object to the form.

20 THE WITNESS: I believe it would be
21 Sandy, but I could be wrong.

22 BY MR. ANDERSON:

23 Q. Can we agree that this was not a
24 thorough investigation of Ethicon's knowledge base
25 concerning whether or not explanted meshes from the

1 pelvis show degradation if your team did not reach
2 out to your pathologist who has actually looked at
3 your explanted meshes for decades? Would you say
4 it's not a thorough review?

5 MR. DAVIS: Object to the form.

6 THE WITNESS: I would not agree with
7 that statement.

8 BY MR. ANDERSON:

9 Q. Do you believe that patients in the
10 UK who are relying upon their regulatory agency and
11 the company Johnson & Johnson/Ethicon who sold them
12 products that were going to be permanently implanted
13 in their body, do you think that they had a right to
14 know and to have information concerning whether or
15 not other women had explanted mesh showing
16 degradation of polypropylene in their vaginas as
17 well?

18 MR. DAVIS: Object to the form.

19 THE WITNESS: If they wanted to look
20 at such information, I don't know if that type of
21 information is available or not.

22 MR. ANDERSON: Motion to strike as
23 nonresponsive.

24 BY MR. ANDERSON:

25 Q. I asked you, if you believe that

1 patients, women, in the UK who were relying upon
2 their regulatory body to be a gatekeeper for safety
3 of medical devices in their country, do you believe
4 those women had a right to expect that your company
5 would provide thorough and accurate information to
6 this regulatory body concerning whether or not
7 polypropylene meshes degrade in a woman's pelvis?

8 MR. DAVIS: Object to the form.

9 THE WITNESS: Well, they would
10 certainly -- well, my opinion is that they could
11 expect that, you know, proper product safety
12 information would have been provided to the
13 regulatory body.

14 BY MR. ANDERSON:

15 Q. How about if the specific product
16 safety information concerns Ethicon's knowledge of
17 its explanted meshes showing degradation by their
18 top pathologist, do you think that might be
19 information they'd want their regulatory body to
20 know?

21 MR. DAVIS: Object to the form.

22 THE WITNESS: It might depend on the
23 circumstances and number of incidences observed.

24 BY MR. ANDERSON:

25 Q. Can I get a yes or a no to my

1 question?

2 A. Well --

3 Q. Do women in this country or the UK,
4 can they rightfully expect that the regulatory
5 agencies who are charged with their safety are being
6 provided with thorough and accurate information by
7 your company as to whether or not polypropylene may
8 degrade in their pelvises?

9 MR. DAVIS: Object to the form.

10 THE WITNESS: Yes, I think they are
11 getting the proper information from Ethicon to the
12 regulatory body.

13 BY MR. ANDERSON:

14 Q. You think they're getting proper
15 information.

16 Proper information would also include
17 thorough information, for instance, when you're
18 doing an investigation on degradation, either do
19 your own study or look to your own consultants and
20 look at their explants. That would be thorough and
21 proper information, not just relying on a seven-year
22 dog study from 25 years ago. Can we at least agree
23 to that?

24 MR. DAVIS: Object to the form.

25 THE WITNESS: You'd want to consider

1 information that you had that's been generated in
2 the past as well as the present.

3 BY MR. ANDERSON:

4 Q. Right.

5 And if part of that information
6 that's been generated in the past is your
7 pathologist and your -- strike that.

8 Maybe I should just take it off
9 because it's...

10 Yes. And if part of the information
11 that's been generated in the past is information
12 that Ethicon has access to from its own pathologist
13 who has looked at explanted samples from a woman's
14 vagina and it shows degradation, that's information
15 that should be passed along to a regulatory body so
16 that they can protect the safety of women in whom
17 these are going to be implanted. Can we agree to
18 that?

19 MR. DAVIS: Object to the form.

20 THE WITNESS: Not necessarily. It
21 depends on the context and the circumstances and the
22 specific type of information and whether it applies.

23 BY MR. ANDERSON:

24 Q. And none of those, the context, nor
25 the circumstances, nor the specific type of

1 information, at least vis-à-vis Dr. Klosterhalfen,
2 was ever considered by your group?

3 MR. DAVIS: Object to the form.

4 BY MR. ANDERSON:

5 Q. That was looking at this in March of
6 2012. Agreed?

7 MR. DAVIS: Object to the form.

8 THE WITNESS: I don't know what
9 information Sandy or Dennis considered from that
10 particular article. I can only answer from my own
11 point of view.

12 BY MR. ANDERSON:

13 Q. If there was a failure of your team
14 to reach out to Dr. Klosterhalfen or to other people
15 within your company to find out what information you
16 had on explanted meshes from either hernia or the
17 pelvis, that would have been a violation of your
18 credo in terms of putting patient safety first.
19 Would you agree to that?

20 MR. DAVIS: Object to the form.

21 BY MR. ANDERSON:

22 Q. Can we agree to that?

23 MR. DAVIS: Object to the form.

24 THE WITNESS: No, I don't necessarily
25 agree with that.

1 MR. ANDERSON: Clave article,
2 Plaintiff's T-277.

3 - - -

4 (Deposition Exhibit No. T-277,
5 Article entitled "Polypropylene as a
6 reinforcement in pelvic surgery is not
7 inert: comparative analysis of 100
8 explants," Arnaud Clave, et al., 10 pages,
9 was marked for identification.)

10 - - -

11 BY MR. ANDERSON:

12 Q. Before we go to that one, I'm going
13 to show you Plaintiff's Exhibit 278.

14 - - -

15 (Deposition Exhibit No. T-278, E-mail
16 chain, top one dated 07 Mar 2012, Bates
17 stamped ETH.MESH.07226404 and
18 ETH.MESH.07226405, was marked for
19 identification.)

20 - - -

21 BY MR. ANDERSON:

22 Q. The last Bates numbers are 6404.

23 If you look at the second page of
24 this document, it's an e-mail from you to Lynn Meyer
25 on March 7, 2012. Do you see that?

1 A. Yes.

2 Q. It says "Any progress on my
3 questions?"

4 What questions were those?

5 A. Questions whether or not there were
6 any -- let's see. Let me refresh my memory here.

7 I wanted to know if there were any
8 product complaint records of preabsorption or
9 degradation.

10 Q. Right. We talked about this a few
11 minutes ago.

12 In your final response to the MHRA,
13 you said, "In the 40 plus" -- I need that. Can I
14 have that?

15 So you were deciding whether or not
16 you could put the language -- if you look at the
17 middle of the first page of this, you were trying to
18 decide whether or not you were going to -- strike
19 that.

20 You asked the question of whether or
21 not there was any complaints on degradation or
22 preabsorption?

23 A. Correct.

24 Q. And they went back and they did in
25 fact found -- find four complaints regarding Prolene

1 sutures that were under degradation or
2 preabsorption. Correct?

3 MR. DAVIS: Object to the form.

4 THE WITNESS: Yes.

5 BY MR. ANDERSON:

6 Q. And it says, and none of those were
7 confirmed.

8 And so then you say in e-mail to
9 Dennis Jamiolkowski, Sandy and Laura on March 7,
10 2012, "From a search that went" back as far" as
11 1991, only four complaints were found concerning
12 PROLENE suture or mesh under the categories
13 'degradation' or 'pre-absorption,'" and "none of
14 those were confirmed.

15 "So, although there have been
16 complaints made on PROLENE about 'degradation' or
17 'pre-absorption,' none were confirmed.

18 "Therefore, you could state that 'In
19 the 40+ year history of PROLENE, there has not been
20 a single confirmed complaint about degradation or
21 absorption.' "

22 Do you see that?

23 A. Yes, I do.

24 Q. Why not just tell the agency that
25 you'd had four unconfirmed reports of degradation or

1 preabsorption?

2 MR. DAVIS: Object to the form.

3 THE WITNESS: You could -- that could
4 have been done.

5 BY MR. ANDERSON:

6 Q. But it wasn't done, was it?

7 A. No.

8 Q. Because it sounded better just to say
9 that there's not been a single confirmed complaint
10 about degradation or absorption?

11 A. Both are true.

12 MR. DAVIS: Wait, wait, wait. Object
13 to the form.

14 BY MR. ANDERSON:

15 Q. Yeah.

16 One is true without telling the whole
17 story so that you're technically right, but you
18 didn't provide all the information to them
19 concerning the fact that you did have four
20 complaints of degradation.

21 MR. DAVIS: Object to the form.

22 BY MR. ANDERSON:

23 Q. Correct?

24 A. The only difference between the two
25 statements is that in the second one it doesn't

1 indicate how many unconfirmed complaints were logged
2 in.

3 Q. You didn't do it because you
4 didn't -- you wanted to wordsmith it in a way that
5 sounded the best for your company instead of
6 providing them with all the information. That's the
7 truth. Correct?

8 MR. DAVIS: Object to the form.

9 THE WITNESS: The only piece of
10 information that's missing is that there were a
11 total of four complaints made, of which none were
12 confirmed. Considering 40 years of the product
13 history to have only four complaints, period, is
14 pretty darn small. And considering that none of
15 them were confirmed...

16 BY MR. ANDERSON:

17 Q. And some, they tried to go back into
18 an old obsolete paper system in Germany, and they
19 couldn't even get a complete file on some of the
20 events. Correct?

21 A. That is correct. There is a file --
22 there is a complaint file that is incomplete
23 apparently. But still, none of the complaints were
24 confirmed.

25 Q. So then above that, Dennis sends an

1 e-mail to Laura that says, "Although we could make
2 the statement that Dan suggested, I think we need to
3 make" it "crystal clear that polypropylene is not
4 100 percent inert in all clinical situations."

5 Do you see that?

6 A. Yes, I do.

7 Q. Do you agree with the statement that
8 polypropylene is not 100 percent inert in all
9 clinical situations?

10 A. It depends on how you define
11 "clinically inert."

12 Q. Well, I've heard of chemically inert
13 and biologically inert, but I've certainly never
14 heard of clinically inert.

15 Is this a new phrase you've come up
16 with or is that something you guys use at Ethicon?

17 MR. DAVIS: Object to the form.

18 THE WITNESS: Well, as the statement
19 was, "We need to make" it "crystal clear that
20 polypropylene is not 100 percent inert in all
21 clinical situations."

22 BY MR. ANDERSON:

23 Q. That means in some clinical
24 situations it actually degrades. Correct?

25 MR. DAVIS: Wait. I think he was

1 still trying to answer the question.

2 BY MR. ANDERSON:

3 Q. Were you still trying to answer the
4 question?

5 MR. DAVIS: I may be wrong, but...

6 THE WITNESS: No. We can move on.

7 MR. DAVIS: Okay.

8 THE WITNESS: I'm sorry, your
9 question was?

10 MR. DAVIS: I apologize.

11 BY MR. ANDERSON:

12 Q. So this statement by definition is,
13 polypropylene is not inert in all clinical
14 situations. Correct?

15 A. Yes, that's what that statement
16 indicates.

17 Q. In what clinical situations did your
18 group determine, through its own testing, validation
19 or literature review where polypropylene may degrade
20 and not be inert in the human body?

21 MR. DAVIS: Object to the form.

22 THE WITNESS: Could you repeat that
23 one more time, please?

24 BY MR. ANDERSON:

25 Q. In what clinical situations did your

1 group determine through its own testing, validation
2 or literature review where polypropylene may degrade
3 and not be inert in the human body?

4 A. I believe that was -- I believe that
5 was acknowledging scenarios where significant
6 infection was present, where you could -- where it
7 would -- where you could expect the possibility of
8 free radicals and oxygen.

9 Q. What's your basis for making that
10 statement, sir?

11 A. Based on the discussion and the
12 response that we made.

13 Q. So based upon what you just said --

14 A. Uh-huh.

15 Q. -- you would have to agree with the
16 Clave authors that in some clinical situations,
17 polypropylene is not inert and it does degrade.

18 MR. DAVIS: Object to the form.

19 BY MR. ANDERSON:

20 Q. True?

21 A. I would agree that there are some --
22 there is some evidence that some of the
23 polypropylene surfaces do undergo some change.
24 That's not totally understood.

25 Q. Okay. Not an answer to my question,

1 so I'll ask it again.

2 Would you agree with the authors of
3 the Clave paper that in some clinical situations,
4 implanted surgical polypropylene mesh in human
5 beings can degrade and is not inert?

6 MR. DAVIS: Object to the form.

7 BY MR. ANDERSON:

8 Q. Yes or no?

9 A. I would say it was subject to some
10 slight degrees of surface degradation, again, which
11 is not completely understood.

12 Q. And it could be better understood if
13 your company undertook the testing of this of its
14 own products that are permanently implanted in
15 women. True?

16 MR. DAVIS: Object to the form.

17 BY MR. ANDERSON:

18 Q. Yes or no?

19 A. If such a study -- if such a study
20 were done, it could possibly give more information
21 about it.

22 Q. But your company has not spent the
23 money nor taken the time to do that study. Correct?

24 A. I'm not aware of any such study being
25 planned.

1 MR. ANDERSON: We can take a break.

2 THE VIDEOGRAPHER: Going off the
3 record. The time is 2:39 p.m. This is the end of
4 Tape 3.

5 - - -

6 (A recess was taken from 2:39 p.m.
7 to 2:58 p.m.)

8 - - -

9 THE VIDEOGRAPHER: We are back on the
10 record. Here marks the beginning of Volume 1 and
11 Tape Number 4 in the deposition of Daniel Burkley.
12 The time is 2:58 p.m.

13 BY MR. ANDERSON:

14 Q. So real briefly, of this group of
15 people who were meeting to discuss Clave, we had Dan
16 Burkley, that's you, from analytical
17 characterization. Correct?

18 A. Yes.

19 Q. Sandy Savidge from preclinical?

20 A. Yes.

21 Q. Laura Vellucci from what department?

22 A. Regulatory affairs.

23 Q. Dennis Jamiolkowski from?

24 A. Suture technology.

25 Q. Anyone else that was regularly at

1 these meetings or involved in this analysis?

2 A. No, no. I believe it was just the
3 four of us.

4 Q. And after that response was sent off
5 to the regulatory body in the UK, have there been
6 any further phone calls, e-mails or meetings
7 concerning the Clave article of which you have been
8 involved in or of which you have been aware?

9 A. No, none that I've been involved in
10 and none that I'm aware of.

11 Q. Okay.

12 So did you have a chance to look at
13 the Clave article, which we marked as Plaintiff's
14 Exhibit T-277? That's the article we've been
15 discussing at length here today. Correct?

16 A. Yep, yep.

17 MR. DAVIS: Let me just note my
18 objection for the record. This was an exhibit to
19 his last deposition and reviewed thoroughly, but I'm
20 not going to stop you. I'm just noting my
21 objection.

22 MR. ANDERSON: I appreciate that.
23 And one of the reasons we're going into it in a
24 little bit more detail is because we received new
25 documents since the time of his deposition and which

1 his name was on, so either we didn't get all of the
2 custodial file or we received it in a later
3 production, and that includes a number of the
4 exhibits that we've used today and other
5 information. And so it made it necessary for us to
6 not replot old ground, hopefully, maybe a little
7 bit, but to also have an opportunity with the
8 benefit of formerly unproduced documents to ask
9 those questions. But I note your objection for the
10 record. Thank you.

11 BY MR. ANDERSON:

12 Q. If you look at the second page of
13 this -- actually, let's -- I'm sorry, let's go back
14 to the first.

15 If you look under the abstract
16 portion, under "Methods," it says, "A sample."

17 You had it right.

18 "Methods." "A sample of 100 implants
19 explanted from patients due to complications was
20 examined to evaluate the relative degradation
21 characteristics of polypropylene and PET
22 prosthetics."

23 And then at the top of the next
24 paragraph, going all the way through "Conclusions."
25 It looks like they did SEM, FTIR, which we discussed

1 earlier, as well as differential scanning
2 calorimetry, DSC.

3 Do you see that?

4 A. Yes.

5 Q. Now, do you ever perform DSC as part
6 of your duties at Ethicon?

7 A. No, I do not.

8 Q. Do you have a machine at Ethicon to
9 perform DSC?

10 A. There is a DSC within analytical
11 characterization.

12 Q. Under "Conclusions," "This is the
13 first study to evaluate synthetic implants used in a
14 vaginal approach for pelvic floor reinforcement.
15 The study provides evidence contrary to published
16 literature characterizing polypropylene as inert in
17 such applications. Additionally, the study suggests
18 the need for clinical trials comparatively
19 investigating the performance of new types of
20 monofilament prosthetics, such as those compromising
21 PET."

22 Do you see that?

23 A. Yes.

24 Q. So at least according to this, this
25 article in January of 2010 written by these authors,

1 was the first one to study that the synthetic
2 implants that had been explanted from a vaginal
3 approach for pelvic floor reinforcement. Correct?

4 MR. DAVIS: Object to the form.

5 THE WITNESS: Yes.

6 BY MR. ANDERSON:

7 Q. When your group met, did you find any
8 other studies prior to this one or after this one
9 where scientists studied and evaluated synthetic
10 explants for pelvic floor reinforcement?

11 A. I don't recall of any studies prior
12 to this one. I don't know if there had been other
13 studies since this one.

14 Q. In order to do a thorough
15 investigation of this problem and to provide a
16 thorough and accurate response to the regulatory
17 body, it would have been a good thing for your group
18 to do a literature search. Correct?

19 MR. DAVIS: Object to the form.

20 THE WITNESS: Yes.

21 BY MR. ANDERSON:

22 Q. Did you do one?

23 A. I did not do a literature search, no.

24 Q. Did Laura, Dennis or Sandy do one?

25 A. I don't know.

1 Q. Did you ask them at any of the
2 meetings, words to the effect of hey, guys, if we're
3 going to provide a response to Clave, shouldn't we
4 look to the literature to see if there's any other
5 similar studies for vaginal explants?

6 A. I did not ask the question, but it's
7 conceivable that that could have been discussed at a
8 meeting where I was not present.

9 Q. And there's a whole host of
10 references in the back of this document.

11 Did you or Sandy or Dennis or Laura
12 take the opportunity to evaluate and analyze any of
13 those bibliographical references listed in the back,
14 of which there are 24?

15 A. I'm familiar with reference 16.

16 Q. And did you bring reference 16 to the
17 group's -- you said you're familiar with it.

18 My question was, as part of your
19 review in coming up with a response to this
20 regulatory body, did you review any articles, so are
21 you in response to saying that, yes, we looked at
22 reference 16?

23 A. I looked at reference 16 but the
24 group did not.

25 Q. What did reference 16 from 1994, the

1 Martin Yang article, "Infrared spectroscopy of the
2 photoxidation of a polyethylene nonwoven fabric,"
3 tell you?

4 A. Well, it demonstrated that
5 photooxidation of a polyolefin, such as
6 polyethylene, it's certainly possible, and some of
7 the IR absorbances that you could observe with it.
8 It's an infrared study, basically, to look at
9 photooxidation of polyethylene fabric.

10 Q. So that study told you that if you
11 look at infrared spectroscopy of this polyolefin,
12 that you could in fact -- that there was degradation
13 noted in that study?

14 A. You could see -- yes, you could see
15 the oxidative degradation by infrared. You could
16 pick up the infrared absorbances specifically
17 relating to photooxidation.

18 Q. Did you raise that to the group's
19 attention?

20 A. No, I did not.

21 Q. Why not?

22 A. It's work I'm familiar with. We've
23 done our own photooxidation studies on polypropylene
24 back in the '80s, so I am familiar with oxidation of
25 polypropylene or photooxidation of polypropylene, I

1 should say.

2 Q. What is photooxidation of
3 polypropylene?

4 A. Basically you're exposing the
5 polypropylene fiber to high intensity light to -- in
6 an air or oxygen-filled environment and over time,
7 seeing the effects of that exposure.

8 Q. Of course, when polypropylene
9 surgical meshes are inserted into a woman's vagina,
10 it's not going to be in an air environment.
11 Correct?

12 A. No, not an air environment.

13 Q. So really reviewing a photooxidation
14 study of polyethylene didn't tell you much in terms
15 of whether or not your polypropylene meshes for the
16 pelvis degrade in the human body?

17 A. Correct.

18 Q. An article that would have been more
19 specific to your research and the mission that you
20 had in trying to determine whether or not your
21 polypropylene meshes show degradation and how to
22 respond to this regulatory body would have probably
23 been something like reference 20, Costello,
24 "Characterization of heavyweight and lightweight
25 polypropylene prosthetic mesh explants from a single

1 patient."

2 Can we agree that that may have
3 provided more valuable information than looking at
4 IR spectroscopy of polyethylene that's exposed to
5 air?

6 MR. DAVIS: Object to the form.

7 THE WITNESS: Possibly, possibly.

8 BY MR. ANDERSON:

9 Q. But you didn't look at that nor raise
10 that to the group's attention, nor did anyone else
11 raise it, did they?

12 MR. DAVIS: Object to the form.

13 THE WITNESS: I don't know if anyone
14 else raised it. I certainly didn't raise it and I
15 didn't -- I was not part of a discussion about that.

16 BY MR. ANDERSON:

17 Q. So if you look at page 2 of this
18 article, under the right-hand column under "Scanning
19 electron microscope analysis," they did a
20 morphological analysis of explants as well as the
21 pristine control mesh samples. Correct?

22 A. Yes.

23 Q. Prior to the doing the imaging, both
24 the explants as well as the pristine samples were
25 fixed and preserved in a solution of cacodylate

1 buffer, then they were rinsed in a buffer and then
2 post fixed.

3 Do you see that?

4 A. Yes.

5 Q. Then they were rinsed with distilled
6 water, dehydrated with ethanol solutions of
7 increasing concentrations, dried using
8 hexamethyldisilazane and then sputtered with gold
9 prior to the SEM analysis. Correct?

10 A. Yes.

11 Q. When you read this portion of
12 Costello, was it your opinion that any part of this
13 preparation led to the surface cracking and peeling
14 as noted in the photographs contained within this
15 article?

16 A. The desiccation effect, when they did
17 the exchanges with ethanol, you know, after it was
18 rinsed with distilled water, that was a possibility
19 that that desiccation effect and/or put in a high
20 vacuum environment, those could have been
21 opportunities of sample manipulation that may have
22 caused that artifact.

23 Q. Could have been.

24 But in fact in this study what they
25 found is, and the reason that they looked at the

1 pristine samples, was so that they could show that
2 the pristine samples in fact were not degraded or
3 have -- I'm sorry, were not subject to surface
4 cracking or peeling as a result of this fixation
5 method. Correct?

6 MR. DAVIS: Object to the form.

7 THE WITNESS: The pristine samples
8 would not, because they can withstand this type of
9 sample preparation. What's not clear is whether the
10 surfaces that were changed could stand this type of
11 sample preparation.

12 BY MR. ANDERSON:

13 Q. Have you ever done any studies or
14 reviewed any studies wherein this type of sample
15 preparation was applied to explants and it was
16 determined that it was causing surface cracking
17 versus in vivo degradation?

18 A. Not a specific study, no.

19 Q. So your conclusion that this may have
20 possibly caused the surface cracking was just based
21 upon general scientific knowledge you have?

22 MR. DAVIS: Object to the form.

23 THE WITNESS: Well, what would
24 have -- I'm sorry.

25 What would have been clarifying and

1 useful information is if they had done any optical
2 examinations after each step of the sample
3 preparation to determine if there were any
4 alterations to the surface.

5 BY MR. ANDERSON:

6 Q. But you have no data and no studies
7 that you can point to that says more likely than
8 not, the cracking that we see in the photos in this
9 article is due to ethanol or a high vacuum
10 environment versus in vivo degradation?

11 MR. DAVIS: Object to the form.

12 BY MR. ANDERSON:

13 Q. That's the truth. Correct? Yes or
14 no?

15 A. No, I have no definitive studies
16 specifically designed to evaluate whether it's an
17 artifact -- whether it's generated as an artifact or
18 whether it's present in the original in vivo
19 environment.

20 Q. So it was conjecture on your part as
21 to whether or not ethanol or high vacuum environment
22 led to some of the surface cracking that was seen on
23 SEM?

24 MR. DAVIS: Object to the form.

25 BY MR. ANDERSON:

1 Q. It's conjecture?

2 A. It's my hypothesis.

3 Q. And you did nothing by way of testing
4 other explanted samples or any sort of testing with
5 any of this treatment method in order to confirm
6 that hypothesis, did you, sir?

7 A. No, I had no such explants available
8 to do such a test with or do such a comparison with.

9 Q. And that goes back to my earlier
10 question.

11 If you had no explants, why didn't
12 you or the group reach out and ask for the explants
13 from Dr. Klosterhalfen?

14 MR. DAVIS: Object to the form.

15 THE WITNESS: That's an interesting
16 proposal. But at the time that this was done, which
17 was written in, what, 2009?

18 BY MR. ANDERSON:

19 Q. Published in 2010.

20 A. Yeah. Well, those explants would be
21 pretty old by then.

22 Q. What if he had already done the
23 analysis and you had it in your own files?

24 MR. DAVIS: Object to the form.

25 BY MR. ANDERSON:

1 Q. That would have been something that
2 you would have liked to have seen. Right?

3 MR. DAVIS: Object to the form.

4 THE WITNESS: If he did that
5 evaluation, yes.

6 BY MR. ANDERSON:

7 Q. And that would have been a thorough
8 investigation by your company as to whether or not
9 your polypropylene product degrades in a woman's
10 pelvis. Yes?

11 MR. DAVIS: Object to the form.

12 THE WITNESS: It would be another
13 piece of information to evaluate. Whether it
14 represents a thorough -- a thorough investigation is
15 conjecture.

16 BY MR. ANDERSON:

17 Q. Well, which is more scientifically
18 valid, sir, your conjecture based on no data
19 whatsoever that the surface cracking was due to
20 ethanol or a high vacuum environment or reaching out
21 to someone who had actual explants and had done
22 analysis of them for your company? Which one is
23 more scientifically valid?

24 MR. DAVIS: Object to the form.

25 THE WITNESS: Well --

1 BY MR. ANDERSON:

2 Q. Between those two, please answer my
3 question.

4 Your conjecture, which is what you
5 said earlier, that it was your conjecture.

6 A. Right. My conjecture is based on the
7 explants that I did back in -- from 1985 to 1992.

8 Q. None of those were vaginal explants,
9 were they?

10 A. No. But they were explants.

11 Q. And we've also determined that
12 vaginal explants are in a bacterial environmental
13 that has greater inflammatory response than other
14 parts of the body. Correct?

15 A. Correct. But it still is an
16 inflammatory or chronic inflammation environment,
17 and you're still talking about polypropylene fibers.

18 Q. Just so the jury understands, what
19 you're telling them under oath today is that some
20 studies you did back in the '80s are just as valid
21 as explanted Ethicon products that were analyzed by
22 your pathologist of 30 years in Germany.

23 Is that what you're telling the jury?

24 MR. DAVIS: Object to the form.

25 THE WITNESS: I'm saying that that

1 information should be considered and can be just as
2 valid.

3 BY MR. ANDERSON:

4 Q. And the -- what did you in the '80s
5 was you looked at a suture coming out of a dog's
6 heart?

7 A. I did.

8 Q. And that's more valid than looking at
9 hundreds of explants and the analysis of them by
10 Ethicon's pathologist.

11 Is that what you're telling the jury?

12 MR. DAVIS: Object to the form.

13 THE WITNESS: I'm not saying it's
14 more valid. I'm saying it's just as valid to
15 examine those explants as it is from examining mesh
16 in a vaginal site.

17 MR. DAVIS: Slow down just a little
18 bit. I know it's getting late. Just pause in case
19 I have an objection.

20 THE WITNESS: Okay. Sorry.

21 - - -

22 (A discussion off the record
23 occurred.)

24 - - -

25 BY MR. ANDERSON:

1 Q. If you look at the next page -- let
2 me ask you this. Let me go back a minute.

3 I'm still trying to communicate with
4 you and get to some understanding of -- and unpack
5 your answers a little bit on this comparing a
6 pristine sample that's been treated in the exact
7 same manner that an explant has been treated. And I
8 believe your testimony has been, well, the ethanol
9 or the high vacuum environment or both would have a
10 different effect on pristine polypropylene than it
11 would on explanted polypropylene.

12 Do I basically have that summarized
13 correctly?

14 A. I'm saying it would have no impact on
15 the pristine polypropylene.

16 Q. And why would it have an impact on
17 the explant that it wouldn't have on the pristine?
18 They're the exact same material.

19 A. That would indicate that that surface
20 has somehow changed.

21 Q. I don't understand your answer. Why,
22 if you -- strike that.

23 If you have the same polypropylene
24 fibers from the same manufacturer, one undergoes the
25 treatment that we saw on page 2 of this study, the

1 explant undergoes the exact same treatment. And of
2 that treatment, you said that the ethanol or the
3 high vacuum environment may be leading to --
4 possibly be leading to the surface cracking. Okay?

5 A. Yes.

6 Q. What is it about the explanted mesh
7 that when treated with the ethanol or the high
8 vacuum environment might lead to surface cracking,
9 whereas the control or pristine sample would not
10 show that?

11 A. The pristine sample would still be --
12 let's see. What's the best way to describe it?

13 The surfaces where the cracking is
14 observed does represent the fact that that surface
15 has undergone some type of change as compared to the
16 pristine areas of the fiber. The pristine areas of
17 the fiber, since they haven't gone through any such
18 change and are basically unchanged normally aren't
19 affected by the sample prep conditions. But there
20 is something about the surface area where the
21 cracking is observed that does respond to the
22 desiccation effect of the sample preparation, and
23 therefore, it behaves differently. We see it as
24 cracking. What's not clear is whether that cracking
25 was present before the sample preparation treatment,

1 because it's obscured by the tissue and/or residual
2 tissue from the explant. And that's my stipulation,
3 is that the sample preparation is what's generating
4 those cracks.

5 Q. Now, you said the pristine areas of
6 the fiber.

7 You understand that they took a fiber
8 out of the box, pristine --

9 A. Right.

10 Q. -- as a control?

11 A. Yeah.

12 Q. There's not some pristine part of the
13 explant.

14 A. Well, there's part -- there's parts
15 of the explant --

16 Q. Can I just --

17 A. I'm sorry.

18 Q. It's really hard for her, so we want
19 to keep Ann Marie happy.

20 If you have a fiber that has never
21 been put into a human body -- we'll get to that.

22 Clave and his colleagues are not
23 coming up with some brand new scientific method in
24 taking a control sample and putting them in a
25 solution and then taking the test sample and putting

1 the same solution in order to determine whether or
2 not you can remove the solution as the cause for
3 what you're finding in the test sample. This is
4 scientific method. This is basic laboratory
5 practice. Can we agree to that?

6 MR. DAVIS: Object to the form.

7 THE WITNESS: The control that's used
8 by Clave is done as a comparison with the explant.
9 And it's been demonstrated that the sample
10 preparation has no impact on the control. All
11 right? And I agree that's part of the scientific
12 method, you want to demonstrate that the control is
13 unaffected by what you're trying to do to the
14 sample, so -- but the control does not have the
15 affected surface that's on the explant.

16 BY MR. ANDERSON:

17 Q. What do you mean by that?

18 A. I mean that there are areas on the
19 surface that is demonstrated by SEM by the cracked
20 regions that have undergone some type of change.

21 Q. How do you know that the cracked
22 region isn't along the entire line of the
23 polypropylene fiber?

24 A. Well, that would be demonstrated by
25 what areas are present, so I mean, if -- it's a

1 large area that's cracked, then that's a large --
2 that's a larger area, surface area that's been
3 impacted. If it's a small area, then it's a small
4 area that's affected.

5 Q. The whole reason that you do this in
6 the first place is so that you can rule out the
7 fact -- strike that.

8 The reason that you use the same
9 solution and the same method on the control as you
10 do the test sample is so that you can rule out the
11 fact that the solution that you used or the
12 preparation method is not affecting the test sample.
13 Right? Correct?

14 MR. DAVIS: Object to the form.

15 THE WITNESS: Right. That you're not
16 impacting the suture itself.

17 BY MR. ANDERSON:

18 Q. Right.

19 And so the reason they did it and the
20 way -- reason that it's a scientific -- basic
21 scientific method, as you've just agreed, is so that
22 you can say, this surface degradation is not due to
23 the sample preparation, and we know that because we
24 used the same sample preparation on the pristine
25 model. Correct?

1 MR. DAVIS: Object to the form.

2 THE WITNESS: That would normally be
3 the logic pattern that's pursued. However, in this
4 instance, all right, you're looking at some surfaces
5 that are alleged to have degraded and/or cracked.
6 If they have been altered, it's not understood that
7 in the original in vivo state whether those surfaces
8 are cracked in the in vivo state or whether those
9 cracks are generated during dehydration of the
10 sample. It's conceivable that in the hydrated
11 state, that that surface could be intact and not
12 have any cracks present.

13 BY MR. ANDERSON:

14 Q. Well, it may be conceivable, but when
15 we look at scientific probability, if the solution
16 and the treatment that's used on the pristine is not
17 causing any surface cracking, and you use the same
18 solution on the explanted mesh, the logical pattern
19 would be that the solution is not causing the
20 cracking, therefore, what is? And that was the
21 basis of what they were doing. Correct?

22 MR. DAVIS: Object to the form.

23 THE WITNESS: That's -- that is their
24 conclusion, but I'm stipulating that what has not
25 been demonstrated is that the sample preparation

1 is -- has no effect at all on the affected area.

2 It's not clear whether the cracks are generated from
3 the sample preparation procedure of the affected
4 areas or whether those affected areas were
5 originally cracked in an implanted state.

6 BY MR. ANDERSON:

7 Q. So you're critical of the study and
8 would be -- and would have a greater level of
9 confidence as to whether or not the sample
10 preparation caused the cracking if they had done
11 optical microscopy during each phase of this
12 preparation prior to SEM. Is that what you're
13 saying?

14 A. Correct, correct. If they had done
15 some type of examination after each sample step to
16 determine if there are any artifacts being generated
17 during the course of the sample prep, that would
18 address my concern.

19 Q. But you certainly cannot, as you sit
20 here today, rule out the fact that the surface
21 cracking on those polypropylene fibers occurred due
22 to in vivo degradation, can you, sir?

23 MR. DAVIS: Object to the form.

24 THE WITNESS: No. The argument I can
25 make is that those cracks that are seen in the SEM

1 images may have been generated during the sample
2 preparation.

3 BY MR. ANDERSON:

4 Q. Yes, but they -- oh, I'm sorry. Go
5 ahead.

6 A. The surface area, it's still a
7 possibility that in the implanted state, those
8 cracks may or may not exist.

9 Q. Right. And I'm working on --
10 You're working on the negative side.
11 I'm working on the positive side.

12 If we're going to say it may have
13 been caused by the sample preparation, we have to
14 also be able to say, scientifically and common
15 sensically, that it may have occurred in vivo prior
16 to the sample preparation.

17 A. Correct.

18 MR. DAVIS: Wait, wait.

19 Object to the form.

20 THE WITNESS: Yeah. I have to --
21 yeah. I'm open to the possibility that the cracks
22 may be present in the in vivo state and that it
23 needs to be determined. That's not a proven point.

24 BY MR. ANDERSON:

25 Q. But you didn't say that in your

1 report that went to this regulatory body that these
2 surface cracks may be present in the in vivo state.
3 I just can't rule it out?

4 A. No.

5 MR. DAVIS: Object to the form.

6 THE WITNESS: I indicated that I
7 believe that these are generated as an artifact
8 during the sample preparation process.

9 BY MR. ANDERSON:

10 Q. But you didn't say it may have been
11 present in the in vivo state, I can't rule that out,
12 did you?

13 MR. DAVIS: Object to the form.

14 THE WITNESS: No, I did not.

15 BY MR. ANDERSON:

16 Q. But that's just what you've told the
17 jury here today. Correct? Yes or no?

18 MR. DAVIS: Object to the form.

19 THE WITNESS: I have told --

20 BY MR. ANDERSON:

21 Q. Yes or no, is that what you just told
22 the jury?

23 A. I'm telling the jury, and I've told
24 the jury on other questions, that the cracks that
25 are generated and observed in the SEM images I

1 believe are artifacts from the sample preparation
2 procedure. I cannot prove it definitively one way
3 or the other, but from my experience with the
4 explants, I believe that this is the case.

5 MR. ANDERSON: Objection, move to
6 strike the answer as nonresponsive.

7 And I'm going to ask you the question
8 again and I'll keep asking it until I get a
9 question -- an answer to my question.

10 BY MR. ANDERSON:

11 Q. You said you told this jury those
12 cracks may have been present in the in vivo state, I
13 can't rule it out.

14 MR. DAVIS: Object to the form -- I'm
15 sorry.

16 BY MR. ANDERSON:

17 Q. However, when you responded to the
18 regulatory agency, you left that out, didn't you?

19 MR. DAVIS: Object to the form.

20 BY MR. ANDERSON:

21 Q. Yes or no?

22 MR. DAVIS: And you're free to
23 explain.

24 MR. ANDERSON: Well, no. I'm free to
25 get a yes or a no. You're welcome to follow up with

1 any questions you want after the deposition, but --

2 MR. DAVIS: I understand, but I do
3 think he answered the question. But he can answer
4 it again.

5 MR. ANDERSON: Yes or no?

6 THE WITNESS: Please repeat it.

7 - - -

8 (The court reporter read the
9 pertinent part of the record.)

10 - - -

11 MR. DAVIS: Object to the form.

12 THE WITNESS: No, I did not make that
13 statement.

14 BY MR. ANDERSON:

15 Q. To this regulatory body in the -- in
16 response to this analysis.

17 A. No.

18 Q. Correct?

19 A. No, it's not in the response.

20 Q. Turn to the next page, please, under
21 the FTIR.

22 And what they did there was before
23 they did FTIR analysis, both prior and after the
24 cleaning, they did it with some sodium hydrochloride
25 and cyclohexane. Correct?

1 A. I'm sorry, where are you looking
2 specifically?

3 Q. Under the FTIR analysis.

4 A. Yes.

5 Q. Now, we talked about SEM. Now I want
6 to talk about the preparation that they did on the
7 FTIR.

8 A. Okay.

9 Q. Okay?
10 They did a baseline IR spectra for
11 all the samples.

12 A. Uh-huh.

13 Q. And then to eliminate the organic
14 residue on the explants, they treated it with --
15 that's probably an O, sodium hydrochloride solution.
16 And they washed that with deionized water, and then
17 they were extracted with pure cyclohexane for 24
18 hours at room temp.

19 Do you see that?

20 A. Yes.

21 Q. The control samples, pristine samples
22 of Prolene and Prolene Soft "were treated with the
23 same protocol to determine if the cleaning process
24 had chemically modified the material."

25 Do you see that?

1 A. I do.

2 Q. And this study indicates that they
3 were not chemically altered as a result of the
4 cleaning process. Correct?

5 A. Yes.

6 Q. So in this instance, regarding FTIR
7 spectroscopy, you don't have any problems with the
8 way they cleaned it as to whether or not this
9 cleaning solution may have led to the cracking. Am
10 I right?

11 MR. DAVIS: Object to the form.

12 THE WITNESS: What's not included
13 here is any type of optical examination to look for
14 any evidence of cracking during each of the sample
15 preparation steps.

16 BY MR. ANDERSON:

17 Q. But they said afterwards, because
18 they looked at the FTIR prior to cleaning and after
19 cleaning in order to compare the two, and they found
20 that there was no desiccation whatsoever as a result
21 of the cleaning process. Correct?

22 A. No. They indicate that they -- that
23 there was no chemical modifications.

24 Q. Can you -- I'm sorry.

25 A. There was no indication about whether

1 they're looking at cracks or not. And my -- you
2 know, what I'm being critical of is whether or not
3 they did any examination of the fiber during the
4 different sample preparation steps to look at and
5 see if there was any evidence of any cracking.

6 Q. But they have FTIR spectroscopy, and
7 they looked at them prior to the solution on both
8 the control and the sample, and then they looked at
9 them afterwards. And on FTIR, there was no -- that
10 the chemical treatment had little to no effect on
11 the material. Correct?

12 A. Correct.

13 Q. So I realize you want the optical
14 microscopy steps in here, but these people who
15 actually did the study and took the time to look at
16 explants, they found that it had no impact on the
17 surface degradation and the cracking. Correct?

18 MR. DAVIS: Object to the form.

19 THE WITNESS: For the control
20 material, that's correct. However, they looked at
21 the explants after the entire sample preparation
22 segment was complete. They did not look at it
23 during different steps. And again, my same point
24 is, is that the cracking could have been generated
25 as a desiccation effect on those affected surfaces

1 that demonstrate cracking in the SEM.

2 BY MR. ANDERSON:

3 Q. If you look at the next page, on the
4 bottom right, next page where it says "FTIR
5 analysis," and they did a chemical analysis?

6 A. Uh-huh.

7 Q. "The FTIR spectra of pristine Prolene
8 and Prolene Soft, before and after the treatment
9 with" the "sodium hydrochloride and cyclohexane,
10 were similar to typical FTIR spectra of
11 polypropylene reported in the literature...
12 Therefore, the chemical treatment had little effect
13 on the material."

14 Do you see that?

15 A. I do.

16 Q. So what you're saying is, it may have
17 had some effect on the explants, you don't know,
18 because you didn't have optical microscopy at every
19 step to be able to look at it. Correct?

20 A. Correct.

21 Q. If the person who actually performed
22 the FTIR analysis and the SEM analysis under oath
23 testified a few months ago that there was no changes
24 during the preparation of these, would you defer to
25 the person who actually did the study versus

1 yourself?

2 MR. DAVIS: Object to the form.

3 THE WITNESS: I'd have to see the
4 type of data he generated.

5 BY MR. ANDERSON:

6 Q. She.

7 A. She.

8 Q. One way you could have found out
9 about the information or the data she generated, if
10 you wanted to do a thorough review of Clave before
11 reporting to a regulatory body, would have been to
12 have contacted them, and all their names and all
13 their locations are listed on the front page of the
14 article on the bottom left.

15 Can you pull that up?

16 MR. DAVIS: Object to the form.

17 BY MR. ANDERSON:

18 Q. You didn't bother to call or e-mail
19 or write to any of these people, did you?

20 A. I did not, no.

21 Q. So instead of criticizing it based
22 upon optimal microscopy sitting in Somerville, New
23 Jersey looking at a piece of paper, in order to
24 provide a thorough response to a regulatory body
25 charged with the safety of women's pelvises, you

1 could have reached out to these folks and asked them
2 what their sample methods and preparations were so
3 that you had a better understanding of their data,
4 couldn't you, sir?

5 MR. DAVIS: Object to the form.

6 THE WITNESS: It's conceivable. I'd
7 have to get permission from the company to make such
8 contact, but yes.

9 BY MR. ANDERSON:

10 Q. Well, do you think that the company
11 would have given you permission to contact someone
12 who's Ethicon's own consultant, Henri Clave?

13 A. It's quite possible.

14 Q. But you didn't even ask?

15 MR. DAVIS: Object to the form.

16 THE WITNESS: No, I did not.

17 BY MR. ANDERSON:

18 Q. If you wanted to do a thorough review
19 before responding to a regulatory body, you would
20 have reached out to these scientists and asked them
21 the same questions I'm asking you. Right?

22 MR. DAVIS: Object to the form.

23 THE WITNESS: It's conceivable that
24 could have been done, yes.

25 BY MR. ANDERSON:

1 Q. So if you look under -- on the third
2 page of the document, so maybe go to the front again
3 and then just count back three pages. Right-hand
4 side, "Histological analysis."

5 They found that there were basically
6 three types of tissue reaction around the explanted
7 meshes. Do you see that?

8 A. Yes.

9 Q. Type 1 would be an infection where
10 they saw PMNs. Correct?

11 A. PMNs?

12 Q. Polymorphonuclear neutrophils?

13 A. I'm sorry, I'm not familiar with that
14 term.

15 Q. That's a hallmark cellular indication
16 of infection in the human body in response to a
17 foreign body reaction.

18 Are you familiar with that?

19 MR. DAVIS: Object to the form.

20 THE WITNESS: No. I'm not a
21 histologist, so I'm not familiar with this area.

22 BY MR. ANDERSON:

23 Q. Nonetheless, type 1 reaction is an
24 infection. Correct?

25 A. It indicates that in the article,

1 yes.

2 Q. And type 2 is chronic inflammation,
3 where they see FBGCs or foreign body giant cells and
4 mononuclear cells. Correct?

5 MR. DAVIS: Object to the form.

6 THE WITNESS: That's what it
7 indicates in the article, yes.

8 BY MR. ANDERSON:

9 Q. Then type 3 was a sclerosis or a
10 pronounced fibrosis.

11 And you've heard about that in terms
12 of fibrotic encapsulation of meshes. Correct?

13 MR. DAVIS: Object to the form.

14 BY MR. ANDERSON:

15 Q. Have you heard about that in response
16 to the body's foreign body reaction to meshes?

17 A. Well, that's the first I've seen
18 this, sclerosis tied to fibrosis. Again, I'm not
19 familiar with these histological terms.

20 Q. If we look at type 1 and type 2, type
21 1 being infection, type 2 being chronic
22 inflammation, those are two of the things that you
23 listed in your response to the regulatory agency --

24 A. Yes.

25 Q. -- as to two of the things that could

1 be --

2 Two of the things that could be
3 related to --

4 Two of the things that could be
5 related to polymer degradation in vivo. Correct?

6 MR. DAVIS: Object to the form.

7 BY MR. ANDERSON:

8 Q. Is that correct?

9 A. I'd have to look at that response.

10 Q. Okay. I'll go back to it.

11 In an infected field, that would be
12 type 1, infection. Correct? And/or a site of
13 chronic inflammation, that would be type 2, it is
14 not unexpected that there will be an increase in
15 free radicals and other reactive oxygen species,
16 polymers may be subject to surface degradation by
17 these reactive species.

18 A. Yep.

19 Q. And here in these articles, these are
20 two of the things listed that they saw in and around
21 what they described as degraded and cracked mesh.
22 Correct?

23 MR. DAVIS: Object to the form.

24 THE WITNESS: Yes.

25 BY MR. ANDERSON:

1 Q. So would you agree with me that if
2 the area surrounding polypropylene mesh in a woman's
3 vagina shows histological evidence of infection and
4 chronic inflammation, that those two factors could
5 lead to degradation of the polymer?

6 MR. DAVIS: Object to the form.

7 THE WITNESS: That environment could
8 promote or could have a population of free radicals
9 and oxygen that could lead to some alteration of the
10 surface.

11 BY MR. ANDERSON:

12 Q. What happens to a woman if the
13 polypropylene in her pelvis -- strike that.

14 You understand that slings made out
15 of Prolene by Ethicon in pelvic organ prolapse mesh
16 made out of Gynemesh PS are going to be permanently
17 implanted in a woman's pelvis. You understand that.
18 Right?

19 A. Yes. They could be permanently
20 implanted, yes.

21 Q. Well, that's the indication, they're
22 supposed to be permanently implanted. Right?

23 A. Yes.

24 Q. So if a woman is 30 years old and
25 she's implanted with one of Johnson &

1 Johnson/Ethicon's polypropylene surgical meshes,
2 either for SUI or POP, can you state to a scientific
3 certainty that that polypropylene will not degrade
4 over the life of the product in her pelvis?

5 MR. DAVIS: Object to the form.

6 THE WITNESS: The product as designed
7 is not absorbable, so, therefore, it should not
8 degrade over the life of the product.

9 BY MR. ANDERSON:

10 Q. However, you've just told the jury,
11 based upon the response that your team gave to this
12 regulatory body in the UK, as well as based upon
13 this study conducted by Clave, that in the presence
14 of infection or chronic inflammation, polypropylene
15 can in fact degrade in a woman's pelvis.

16 MR. DAVIS: Object to the form.

17 BY MR. ANDERSON:

18 Q. Correct?

19 A. There is some suggestions of surface
20 alterations. There has been no indication that I've
21 seen of actual product failure in terms of its
22 strength, and from the studies that I've looked at,
23 no evidence of overall loss in molecular weight.
24 And in the data that's in the Clave study, their DSC
25 indicates no significant changes between the

1 pristine and the explanted material. So the
2 infrared study does show some observations of
3 absorbances, but they cannot conclude whether this
4 was oxidation or whether it was residual proteins or
5 tissue. So I can't say there's any concrete
6 evidence that there was any significant degradation
7 present.

8 Q. And you don't have any concrete
9 evidence that polypropylene doesn't degrade in a
10 woman's pelvis either, do you?

11 MR. DAVIS: Object to the form.

12 THE WITNESS: I have only -- I have
13 no personal data, but the company does have clinical
14 data and preclinical data on other Prolene products.

15 BY MR. ANDERSON:

16 Q. We've gone through this before.

17 The only data that you have regarding
18 degradation is a suture from a dog heart from the
19 mid '80s when it comes to degradation and your
20 company looking at SEMs of those. Correct, sir?

21 MR. DAVIS: Object to the form.

22 THE WITNESS: From my studies, yes.

23 BY MR. ANDERSON:

24 Q. What other degradation -- you
25 qualified that.

1 I thought earlier we maintained that
2 out of your 34 years, you've never seen any
3 degradation studies other than -- if you called it a
4 degradation study, it was actually a comparative
5 study of your sutures.

6 So in your 34 years at Ethicon, you
7 have not seen, nor are you aware of, any degradation
8 studies performed by your company in order to
9 determine whether or not polypropylene degrades in
10 the human body?

11 MR. DAVIS: Object to the form.

12 THE WITNESS: That's correct. I am
13 unaware of any existing studies.

14 BY MR. ANDERSON:

15 Q. Okay.

16 So now we're going back to your
17 answer, because you listed all of these things. You
18 listed clinical experience, you listed studies that
19 were done, et cetera. I want to unpack that and get
20 down to nuts and bolts here. Okay? So here's my
21 question.

22 You were making the assumption that
23 polypropylene will not degrade in a woman's pelvis
24 over her lifetime on a seven-year dog study that was
25 conducted from a suture from the dog's heart

1 conducted in the mid '80s when it comes to
2 degradation?

3 A. That's part of --

4 MR. DAVIS: Wait. Object to the
5 form.

6 THE WITNESS: That is part of the
7 information I'm relying on.

8 BY MR. ANDERSON:

9 Q. If you look at the SEM photographs on
10 page 265, the upper right says "265" and the word
11 "degraded." If you look at those SEM photographs.

12 A. Uh-huh.

13 Q. There's a low density monofilament,
14 like Prolene Soft, and a high density polypropylene
15 monofilament like Prolene pictured there. Correct?

16 A. Yes.

17 Q. And on the left we see no surface
18 cracking and no surface peeling, whereas on the
19 right, in both, we do see surface cracking and
20 perhaps peeling on the bottom with the high density
21 being worse by observation than the one above it.

22 Can we agree to that observation of
23 these photographs?

24 A. Yes.

25 Q. Okay.

1 When you saw those photographs and
2 your team saw those photographs, was there a
3 discussion amongst you as to what the clinical
4 implications would be to a woman if these explants
5 looked like this -- strike that.

6 These were taken out after three
7 months. Correct? Degradation started appearing at
8 90 days. Correct?

9 A. In some instances, according to their
10 article, yes.

11 Q. So if you see this kind of cracking
12 at 30 days, if in fact this is degrading in a woman,
13 was there a discussion as to whether or not this
14 would have any clinical implications in 20 years?

15 MR. DAVIS: Object to the form.

16 THE WITNESS: There was a discussion
17 relating to the seven-year dog study where
18 surfaces -- where polypropylene sutures, and in some
19 cases other sutures, had demonstrated this similar
20 type of surface cracking, not only at seven years
21 but at earlier time points.

22 But yet at the end of seven years,
23 the testing done indicated that the molecular weight
24 of the polypropylene was essentially unchanged and
25 that the tensile strength of the suture was at least

1 90 percent or greater. So that indicated that
2 although this observation is made, it's apparently a
3 relatively insignificant effect in terms of the
4 performance of the device.

5 BY MR. ANDERSON:

6 Q. Are you aware that Johnson & Johnson
7 and Ethicon's own expert in this litigation, Dr.
8 David Williams, sat in the exact chair you're
9 sitting in a month after you testified and said that
10 polypropylene does degrade in the human body?

11 MR. DAVIS: I object to the form.

12 BY MR. ANDERSON:

13 Q. Are you aware of that, sir?

14 MR. DAVIS: Object to the form of
15 that.

16 THE WITNESS: No, I am not aware of
17 that.

18 BY MR. ANDERSON:

19 Q. Have you read any of his articles
20 from 1976 forward over the last 40 years regarding
21 polypropylene degrading in the human body?

22 MR. DAVIS: Object to the form.

23 THE WITNESS: I'm aware of some
24 articles that allege that polypropylene degrades.

25 BY MR. ANDERSON:

1 Q. He studied this for 40 years --

2 MR. DAVIS: Wait, wait. I think he's
3 still answering.

4 BY MR. ANDERSON:

5 Q. Were you through?

6 A. No, I'm not through.

7 Q. Okay. Keep talking. Please, I
8 didn't mean that disrespectfully.

9 A. And although these images look very
10 graphic and they look very significant, it's been --
11 I've seen very similar images or even things that
12 look worse than this, but the overall impact to the
13 device itself appears to be minimal to no effect.

14 Q. You said the overall impact to the
15 device.

16 What about the overall impact to the
17 patient?

18 MR. DAVIS: Object to the form.

19 BY MR. ANDERSON:

20 Q. What does surface degradation and
21 polypropylene degrading in a woman's pelvis, what
22 about her impact?

23 MR. DAVIS: Object to the form.

24 BY MR. ANDERSON:

25 Q. Tell me what that would do to a woman

1 in her tissue if this is in fact degrading. Forget
2 the impact to the device. What about the impact to
3 women?

4 MR. DAVIS: Object to the form.

5 THE WITNESS: It hasn't been
6 established and is still not clear in my mind that
7 the cracking phenomenon itself is present in vivo.
8 Nonetheless, if there are surfaces that are being
9 affected during chronic inflammation, they are
10 localized and there is no evidence that I've seen
11 that the performance of the device itself has been
12 impacted by it.

13 BY MR. ANDERSON:

14 Q. Severe and chronic inflammation -- if
15 you want to talk about impact on the device, severe
16 and chronic inflammation can lead to fibrotic
17 bridging and complete encapsulation of the mesh in
18 scar tissue leading to contraction and nerve injury.

19 Do you understand that?

20 MR. DAVIS: Object to the form.

21 THE WITNESS: Yes.

22 BY MR. ANDERSON:

23 Q. And that's not just -- that might be
24 localized to a site, and so would the woman's pain
25 associated with that, too. It would be localized to

1 that site. Correct?

2 MR. DAVIS: Object to the form.

3 THE WITNESS: For an infection site,
4 yes, it would be.

5 BY MR. ANDERSON:

6 Q. And for a chronic inflammatory
7 response as well?

8 A. Yes.

9 Q. If in fact there is a rough surface
10 like this in the woman's tissue in an implant that
11 is moving in tissue, that would increase the
12 inflammatory response, would it not?

13 MR. DAVIS: Object to the form.

14 THE WITNESS: It's possible. It
15 depends on the circumstances.

16 BY MR. ANDERSON:

17 Q. So if there's a possibility that
18 surface cracking of polypropylene fibers increases
19 the inflammatory response, that could also increase
20 the amount of fibrosis in and around the implant.

21 Correct?

22 MR. DAVIS: Object to the form.

23 THE WITNESS: These are
24 possibilities.

25 BY MR. ANDERSON:

1 Q. Well, we know from Ethicon's own
2 investigation and studies that if you increase the
3 inflammatory response, it increases the fibrosing
4 around the implant and causes contraction and pain.
5 Correct?

6 MR. DAVIS: Object to the form.

7 THE WITNESS: I'm not necessarily
8 familiar with the details of that, no. I can't make
9 that conclusion one way or the other.

10 BY MR. ANDERSON:

11 Q. Well, here's the way, here's the
12 thing.

13 Again, I'm not trying to be
14 disrespectful, but you can't have it both ways. You
15 can't, on the one hand, say this surface cracking
16 and some chronic inflammation is localized and
17 doesn't have any impact. And then when I say that
18 your company is aware that a greater inflammatory
19 response can cause contraction of the mesh, pain,
20 nerve injury and erosions and say, oh, I don't know
21 about that.

22 A. Well, I'm responding as an analytical
23 chemist that has examined these types of devices and
24 explants before. So I'm commenting on the surfaces
25 of the explants. I'm not an expert in histology and

1 I'm not an expert in preclinical or clinical
2 aspects. So when you start talking about
3 inflammation sites and scarring, these are areas I'm
4 unfamiliar with.

5 Q. Right.

6 With all due respect, you said that
7 being someone who's familiar with looking at these
8 explants and you pointed to those.

9 Truth is, you're not familiar with
10 looking at any explants ever in your 34 years that
11 came from a woman's pelvis, are you?

12 MR. DAVIS: Object to the form.

13 THE WITNESS: Not from a woman's
14 pelvis. I am -- I have experience looking at
15 explants from animals.

16 BY MR. ANDERSON:

17 Q. Other than the dog study, what
18 explants from animals have you looked at under SEM?

19 A. I can only recall the dog explants.

20 Q. Okay.

21 So there weren't explants from
22 animals --

23 MR. DAVIS: He wasn't through.

24 BY MR. ANDERSON:

25 Q. Oh.

1 A. I'd have to refresh my memory if I've
2 ever looked at any other examples from any other
3 animal types.

4 Q. Well, if you're going to tell the
5 jury under oath that you have this experience by
6 looking at explants from other animals, I have a
7 right to ask you which animals. And all I've heard
8 from you this time and the last time I deposed you
9 was one dog study in the '80s.

10 A. Then I should correct it to say only
11 dogs.

12 Q. So when you point at these pictures
13 here, all you've looked at is one suture from a
14 dog's heart. You haven't looked at 100 explants
15 from women's vaginal space in order to do an SEM or
16 an FTIR or a DSC analysis in order to determine
17 whether or not they are degrading in a woman's
18 pelvis, have you, sir?

19 MR. DAVIS: Object to the form.

20 BY MR. ANDERSON:

21 Q. Yes or no?

22 MR. DAVIS: Object to the form.

23 THE WITNESS: No, but I've looked at
24 several explants from the dog studies at various
25 time points. So it's not just simply one explant.

1 And there were other testing done besides scanning
2 electron microscopy. Those examinations include
3 molecular weight and physical testing.

4 BY MR. ANDERSON:

5 Q. You looked at a fiber a few inches
6 long. That's what you looked at. Right?

7 A. Correct.

8 Q. You've mentioned molecular weight a
9 few times, so let me ask you this.

10 If in fact a scientist were to
11 perform a study and they actually spent the time,
12 money and effort to look at explants from a woman's
13 vagina and compare the pristine fiber of, let's say
14 Prolene to the explanted fiber of Prolene, and there
15 was a loss of molecular weight, there was evidence
16 of chronic inflammation and infection, would that
17 lead you in the direction of perhaps there was
18 degradation of that polypropylene fiber?

19 MR. DAVIS: Object to the form.

20 THE WITNESS: The loss of molecular
21 weight would suggest possible degradation of the
22 Prolene.

23 BY MR. ANDERSON:

24 Q. Okay.

25 So you just haven't seen any studies

1 wherein explanted surgical polypropylene mesh was
2 compared to pristine polypropylene mesh in which
3 there was a drop in molecular weight of the
4 explanted mesh that would help you out in making
5 that determination. Correct?

6 MR. DAVIS: Object to the form.

7 THE WITNESS: I have not seen that
8 type of evidence.

9 BY MR. ANDERSON:

10 Q. If you look at the page that has --
11 that says 267 up in the upper right corner, turn to
12 the page just before that, and we're going to carry
13 over from the bottom of the page you have your
14 finger on there, the bottom right.

15 "Several hypotheses concerning the
16 degradation of the polypropylene are described
17 below. None of these, particularly direct
18 oxidation, could be confirmed in this study."

19 And then you look at the next page,
20 and we have small Roman numeral i, ii and iii.

21 Do you see those?

22 A. Yes.

23 Q. The three hypotheses for the surface
24 degradation are "direct oxidation of the
25 polypropylene," "fatty acid diffusion" or "oxidation

1 due to free radical attack."

2 Do you see that?

3 A. Yes.

4 Q. And free radical attack and oxidation
5 is one of the things that's listed in Ethicon's
6 response to Clare Huntington. Correct?

7 A. Yes.

8 Q. And one of the ways that you would
9 see a greater free radical attack response and
10 oxidation would be in the presence of an infected
11 field or chronic inflammation. Correct?

12 A. That's one example, yes.

13 Q. If you look at the top right of the
14 next column, "The chronic inflammatory reaction may
15 infer free radical synthesis as peroxide and
16 superoxide ions and hypochlorite acid."

17 Do you see that?

18 A. I do.

19 Q. The human body produces peroxide, in
20 particular hydrogen peroxide, does it not?

21 MR. DAVIS: Object to the form.

22 BY MR. ANDERSON:

23 Q. I'm sorry, that's a bad way of asking
24 the question.

25 Let's take a woman. A woman's body

1 produces hydrogen peroxide and other strong
2 peroxides. Correct?

3 MR. DAVIS: Object to the form.

4 THE WITNESS: I don't know the
5 specific circumstances where that would occur,
6 unless that's a cellular -- extracellular response.
7 But I'm not personally knowledgeable nor an
8 authority to indicate whether they do or not.

9 BY MR. ANDERSON:

10 Q. So a woman's body may produce
11 peroxides and in particular hydrogen peroxide, you
12 just don't know?

13 A. I don't know. That's correct.

14 MR. DAVIS: Object to the form.

15 BY MR. ANDERSON:

16 Q. If it does, that would be one thing
17 that would infer a free radical synthesis. Correct?

18 MR. DAVIS: Object to the form.

19 THE WITNESS: That is one hypothesis
20 explained here in this article, yes.

21 BY MR. ANDERSON:

22 Q. A woman also has in her vaginal
23 space, in her body, but in this instance where the
24 mesh is located in her vaginal space, hypochlorite
25 acid, does she not?

1 MR. DAVIS: Object to the form.

2 THE WITNESS: I can't comment on
3 that.

4 BY MR. ANDERSON:

5 Q. If in fact a woman has strong
6 peroxide and hypochlorite acid in her body and it
7 induces a chronic inflammatory reaction, that in
8 fact could account for surface degradation of
9 polypropylene. Correct?

10 MR. DAVIS: Object to the form.

11 THE WITNESS: It's one hypothesis
12 stated in this article, yes.

13 BY MR. ANDERSON:

14 Q. Well, I'm not asking if that's just a
15 hypothesis, I'm asking you, because you have given
16 your opinion on things, you've looked at this, some
17 things you agree with, most you don't. So with all
18 due respect, I'm not asking what they -- I know what
19 they said, it's right here. I'm asking you, because
20 you had provided a response to this agency. So
21 that's the backdrop of my question.

22 A. Right, right.

23 Q. So if a woman has strong peroxides
24 and hypochlorite acid that's produced and it's in
25 and around this mesh, it can in fact lead to

1 degradation of the mesh --

2 MR. DAVIS: Object to the form.

3 BY MR. ANDERSON:

4 Q. -- in some women. Correct?

5 MR. DAVIS: Object to the form.

6 THE WITNESS: In that environment,
7 it's possible it could have -- it could impact the
8 surface.

9 BY MR. ANDERSON:

10 Q. In a septic environment or a
11 contaminated environment like surgical meshes for a
12 woman's vagina are placed, also when you have
13 hematoma and bruising, fatty acids are produced by
14 the woman in response to those two things that could
15 also lead to degradation. Correct?

16 MR. DAVIS: Object to the form.

17 THE WITNESS: I'm not -- I can't
18 comment on that. I don't know that for a fact or
19 not.

20 BY MR. ANDERSON:

21 Q. And if you see carboxyl groups on
22 FTIR, that could also be related to direct oxidation
23 of polypropylene, could it not?

24 MR. DAVIS: Object to the form.

25 THE WITNESS: It could be related to

1 oxidation. It could be related to residual
2 proteins.

3 BY MR. ANDERSON:

4 Q. If we had a bacterial environment
5 with a chronic inflammatory response in the presence
6 of hydrochloride acid and strong peroxides like
7 hydrogen peroxide, in some women that can in fact
8 degrade the polypropylene in their pelvis. Would
9 you agree with that?

10 MR. DAVIS: Object to the form.

11 THE WITNESS: In that environment, it
12 could possibly have an impact on the surface of the
13 polypropylene fibers.

14 BY MR. ANDERSON:

15 Q. And it could in fact cause it to
16 degrade and lose molecular weight. Correct?

17 A. I do not agree with that statement.

18 Q. You have no basis for stating that
19 you disagree with it other than your dog study in
20 the '80s?

21 MR. DAVIS: Object to the form.

22 THE WITNESS: That data -- yes, I'm
23 relying on that data.

24 BY MR. ANDERSON:

25 Q. If you look right above "Conclusion"

1 on page 269, it says 269 up at the top.

2 Right above the word "Conclusion,"
3 that last sentence, "Additional chemical analysis
4 such as thermogravimetric analysis and molecular
5 weight determination, specifically, would further
6 clarify the mode of prosthetic damage."

7 Do you see that?

8 A. Yes.

9 Q. After you read that and before you
10 guys decided to give a response to the UK regulatory
11 authority, what thermogravimetric analysis and
12 molecular weight determinations did you do on
13 explanted meshes from a woman's pelvis?

14 MR. DAVIS: Object to the form.

15 THE WITNESS: I'm not aware of any
16 testing that we have done on any explanted meshes
17 from women's pelvises.

18 BY MR. ANDERSON:

19 Q. Is it your testimony to the jury
20 today that the reason that Johnson & Johnson and
21 Ethicon has not conducted any degradation studies
22 like the Clave study in which explanted Ethicon
23 meshes have been compared to pristine Ethicon meshes
24 is because there's no need to, we have a seven-year
25 dog study from the '80s?

1 MR. DAVIS: Object to the form.

2 THE WITNESS: The clinical history of
3 the Prolene line of products --

4 BY MR. ANDERSON:

5 Q. I need to know -- I need to know if
6 that is your testimony. That's a yes or no.
7 Because I don't want to go back through the clinical
8 history and all those things. Quite frankly, you've
9 had a great opportunity to lay that out on the
10 record. I understand your story line. Okay? My
11 question is a little different.

12 I don't, quite frankly, and with all
13 due respect, care about 40 years of clinical
14 history, because I'm talking about a very specific
15 study here and we're talking about degradation.
16 Okay? So that's the context of my question.

17 A. Right.

18 MR. ANDERSON: Can you read back my
19 question, please?

20 - - -

21 (The court reporter read the
22 pertinent part of the record.)

23 - - -

24 MR. DAVIS: And I will remind the
25 witness that while he -- if he can answer yes or no,

1 he should, but he's always free to explain every
2 answer.

3 MR. ANDERSON: Actually, no. I'm
4 entitled to a yes or no, and you have the right to
5 ask him any questions you want at the end of the
6 deposition.

7 MR. DAVIS: I'm going to instruct the
8 witness that my understanding of the rule is you are
9 entitled to explain your answer. But if it can be
10 answered yes or no, you should certainly do that. I
11 agree with counsel opposite, but you do have a right
12 to explain your answer.

13 MR. ANDERSON: I respectfully
14 disagree with that and it's certainly not the rule
15 in Ohio -- I mean the rule in New Jersey.

16 BY MR. ANDERSON:

17 Q. Go ahead. Can you answer that yes or
18 no?

19 A. I can't -- I cannot answer it yes or
20 no. The reason I can't answer it yes or no is I
21 can't speak on behalf of the company as a business
22 decision why they would not pursue such a study as
23 you've indicated. If I had to speculate, I would
24 say that it would be based -- that their decision
25 would be based that there was not a sufficient need

1 at this time to warrant such a study based on the
2 clinical information on the Prolene line of
3 products, and the information already gathered on
4 other studies such as the seven-year dog study, on
5 other Prolene-type products, since they are made
6 from the same type of polypropylene fibers.

7 BY MR. ANDERSON:

8 Q. At the time that you responded a
9 little over a year ago to this regulatory body, did
10 Ethicon and Johnson & Johnson have access to
11 explanted tissue and material of its products from
12 women?

13 MR. DAVIS: Object to the form.

14 THE WITNESS: I do not know.

15 BY MR. ANDERSON:

16 Q. Did anyone on your team reach out
17 within the company, send a company-wide e-mail,
18 send an e-mail to anyone in pathology, and ask, do
19 we have any explanted mesh samples or access to our
20 explanted mesh samples that we could perform an
21 analysis of?

22 MR. DAVIS: Object to the form.

23 BY MR. ANDERSON:

24 Q. Did your team do that?

25 A. I'm not aware of any such inquiry.

1 Q. Now, Joerg Holste is your counterpart
2 in Norderstedt, in the Ethicon Norderstedt facility.
3 Correct?

4 A. He was a member of corporate product
5 characterization, but he was stationed over in
6 Norderstedt.

7 Q. And if you testified at your first
8 deposition that he was your counterpart in Ethicon
9 Norderstedt, any reason that you wouldn't agree with
10 that today?

11 A. He was a member of the department.
12 By counterpart, he does not have -- he did not have
13 the same role I had within corporate product
14 characterization. So he was -- you know, he was
15 certainly another associate within the department.

16 Q. I show you Plaintiff's T-279, last
17 four digits 6636.

18 - - -

19 (Deposition Exhibit No. T-279,
20 Interim report mesh explants pelvic floor
21 repair, April 2008, Bates stamped
22 ETH.MESH.00006636, was marked for
23 identification.)

24 - - -

25 BY MR. ANDERSON:

1 Q. At the top it says "Interim report
2 mesh explants pelvic floor repair, April 2008,
3 Professor B. Klosterhalfen, Institute of Pathology
4 Duren Hospital" in "Germany."

5 Do you see that?

6 A. I do.

7 Q. Down at the bottom, you see that this
8 was translated by Joerg Holste in April of 2008, a
9 senior research fellow for Ethicon in -- we just
10 said in Norderstedt. Correct?

11 A. Yes, I believe that's where he's
12 located.

13 Q. Okay.

14 Either way, Joerg Holste is an
15 Ethicon employee?

16 A. He is.

17 Q. So he translated this document in
18 April of 2008 of 100 explanted mesh samples. And
19 these are mesh explants for the pelvic floor. And
20 that, of course, is what Clave was looking at, 100
21 explants from the pelvic floor. Correct?

22 A. Yes.

23 Q. It says, the "most serious
24 complication following mesh implantation in pelvic
25 floor was mesh erosion in 80 to 90% of the cases."

1 It says, "Mesh erosion is nearly 100% combined with
2 secondary mesh/surgical site infection...
3 Developing a mesh ulceration follows this
4 infection."

5 Then it says under 3, "All meshes
6 without exception induce typical foreign body tissue
7 reaction known from mesh implants in hernia
8 surgery."

9 Number 4, "Foreign body tissue
10 reaction FBR induces fibrosis in the mesh implant
11 area, i.e. severe foreign body reaction is
12 associated with severe fibrosis."

13 5, "Severe fibrotic tissue reaction
14 is often associated with degenerative
15 calcification."

16 Do you see that?

17 A. Yes.

18 Q. Do you think it would have been
19 helpful for your team to have reached out to Dr.
20 Klosterhalfen, who five years prior to you giving
21 this response -- four years prior to you giving this
22 response to this regulatory body, had looked at 100
23 explant meshes and given a report to your company
24 about them?

25 MR. DAVIS: Object to the form.

1 BY MR. ANDERSON:

2 Q. Don't you think that would have been
3 helpful as part of your investigation?

4 A. It's possible that information could
5 have been useful.

6 Q. Now that you've seen this report and
7 you know that Prof. Klosterhalfen has explants, are
8 you going to go back and suggest to your team that
9 perhaps we should do similar Clave analysis on
10 explanted meshes that we have under our control so
11 that we can try to determine whether or not there's
12 degradation of these --

13 MR. DAVIS: Object to the form.

14 BY MR. ANDERSON:

15 Q. -- that may be associated with
16 complications in women?

17 MR. DAVIS: Object to the form.

18 THE WITNESS: Well, the issue
19 associated with explants that are -- have already
20 been explanted and are old is how they're being
21 preserved, and whether or not they're preserved has
22 an impact on the areas that we're interested in
23 examining.

24 BY MR. ANDERSON:

25 Q. If he has evidence,

1 histopathologically or on any of the analyses that
2 he has done of explanted pelvic floor meshes
3 indicating degeneration or degradation of the
4 polypropylene fibers, don't you think that would be
5 information that should be provided to the
6 regulatory body who asked you this question a year
7 ago?

8 MR. DAVIS: Object to the form.

9 THE WITNESS: I don't know if that
10 particular type of information would be applicable
11 or related to the inquiry. And the reason I say
12 that is I'm not a clinician and I'm not -- you know,
13 I don't have preclinical expertise to determine if
14 these types of observations have any significance
15 with the question about -- that the regulatory body
16 had about the polypropylene pelvic floor mesh
17 device.

18 BY MR. ANDERSON:

19 Q. Well, you made a statement in that --
20 your signed statement to this regulatory body that
21 says, "With Prolene suture, there have been no
22 observations of fiber degradation in complaints
23 received and/or products returned."

24 If you wanted to make a full
25 statement back to them now and say, you know what, a

1 year ago we told you that we don't -- we've never
2 had any observations of fiber degradation; however,
3 we've reached out to our pathologist in Germany who
4 has hundreds of our explants and what we've found is
5 there actually is degradation.

6 You don't have to be a clinician to
7 be able to provide that information, do you, sir?

8 MR. DAVIS: Object to the form.

9 BY MR. ANDERSON:

10 Q. And please answer my question.

11 A. I see --

12 Q. Do you have to be a clinician to
13 provide that information, or is that something on
14 your own you could do as part of this group that
15 responded to this regulatory agency?

16 MR. DAVIS: Object to the form.

17 THE WITNESS: I don't know how to
18 answer that question, because the question that you
19 asked me before involves specific points on this
20 memo. And my response was that, you know, I'm not a
21 clinician and I'm not a preclinical expert to
22 determine whether or not these observations are
23 directly related to that. Then you started talking
24 about fibers, fiber degeneration, but this does not
25 talk about any kind of fiber degeneration.

1 BY MR. ANDERSON:

2 Q. I'll ask you my question again.

3 In order to provide a thorough,
4 truthful and accurate response to this regulatory
5 agency, even though it's a year after you gave your
6 first response, wouldn't it be a responsible
7 credo-based action to actually reach out to Prof.
8 Klosterhalfen and ask him if he has seen in his
9 samples evidence of degradation? That's my
10 question.

11 MR. DAVIS: Object to the form.

12 THE WITNESS: I'd have to discuss
13 that with the rest of the team.

14 BY MR. ANDERSON:

15 Q. Don't you think you ought to do that?

16 MR. DAVIS: Object to the form.

17 THE WITNESS: Well, it's worth
18 consulting the team.

19 BY MR. ANDERSON:

20 Q. Can we agree, just as a basic common
21 sensical principle of credo-based, ethical medical
22 device manufacturing that if you've got information
23 that may be helpful to patient safety, even if it
24 hurts the bottom line of the company, you ought to
25 be providing that to regulatory agencies or doctors

1 or patients?

2 MR. DAVIS: Object to the form.

3 THE WITNESS: I can't agree to that
4 statement.

5 BY MR. ANDERSON:

6 Q. If you have information in the form
7 of Ethicon/Johnson & Johnson explanted pelvic floor
8 meshes, which have been analyzed pathologically,
9 histopathologically and other forms of analytical
10 characterization that are sitting in Duren, Germany,
11 would it be credo-based, ethical conduct by your
12 company to try to determine that information so that
13 you could provide that information to Ms. Clare
14 Huntington?

15 MR. DAVIS: Object to the form.

16 THE WITNESS: The observations noted
17 in the article and that are described on here I'm
18 sure would be evaluated by the appropriate
19 professionals and determined, you know, whether
20 these observations are significant enough to be
21 included in such a discussion. But I don't have
22 the -- you know, the overall expertise to make that
23 kind of a judgment call.

24 BY MR. ANDERSON:

25 Q. So in other words, yes, Mr. Anderson,

1 in order to be an ethical, credo-based company who
2 has patient safety first, we should reach out to
3 Prof. Klosterhalfen to see if any of our explanted
4 meshes show degeneration so that we can inform
5 regulatory bodies, doctors and patients that there
6 is a chance that polypropylene could degrade in
7 their pelvises?

8 MR. DAVIS: Object to the form.

9 THE WITNESS: That's not my
10 conclusion.

11 - - -

12 (Deposition Exhibit No. T-280,
13 Intermediate Report -- Prolapse Mesh
14 Explants 6/2009, Bates stamped
15 ETH.MESH.02157879 and ETH.MESH.02157880,
16 was marked for identification.)

17 - - -

18 BY MR. ANDERSON:

19 Q. Let's look at T-280, last four 7879.
20 Did I give you the right one, 7879?

21 A. Yes.

22 Q. Okay.

23 This is a little over a year later,
24 another intermediate report from prolapse mesh
25 explains in June of 2009 where Prof. Klosterhalfen

1 is saying that he's analyzed 172 mesh explants from
2 different manufacturers.

3 If you look down at number 5, "Strong
4 fibrosis is associated with degradation" and
5 "calcification to a greater than average extent."

6 Do you see that?

7 A. Yes. But what's not clear to me is
8 what he means by degradation/calcification and
9 whether that's supposed to be the same as
10 degenerative calcification.

11 Q. So wouldn't it be great to have had
12 these for your group so that you could have asked
13 him?

14 MR. DAVIS: Object to the form.

15 BY MR. ANDERSON:

16 Q. You don't know because no one asked.
17 Correct, sir?

18 MR. DAVIS: Object to the form.

19 THE WITNESS: Well, I don't know
20 under what circumstances this type of study was
21 requested. And being an analytical chemist, there's
22 a lot of information here that is outside my area of
23 expertise.

24 BY MR. ANDERSON:

25 Q. Right.

1 And that's why you had different
2 specialties on your group?

3 A. That's correct.

4 Q. And no one reached out to Prof.
5 Klosterhalfen for this response, did they?

6 MR. DAVIS: Object to the form.

7 BY MR. ANDERSON:

8 Q. That you're aware of?

9 A. I'm not aware of that, no.

10 THE VIDEOGRAPHER: Going off the
11 record. The time is 4:22 p.m. This is the end of
12 Tape Number 4.

13 (Deposition adjourned at
14 approximately 4:22 p.m.)

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CERTIFICATE

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I HEREBY CERTIFY that the witness was
duly sworn by me and that the deposition is a true
record of the testimony given by the witness.

8

9

It was requested before completion of
the deposition that the witness, DANIEL F. BURKLEY,
MS, have the opportunity to read and sign the
deposition transcript.

13

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ANN MARIE MITCHELL, a Federally Approved
Certified Realtime Reporter, Registered
Diplomate Reporter and Notary Public

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(The foregoing certification of this
transcript does not apply to any reproduction of the
same by any means, unless under the direct control
and/or supervision of the certifying reporter.)

1 INSTRUCTIONS TO WITNESS

2

3 Please read your deposition over
4 carefully and make any necessary corrections. You
5 should state the reason in the appropriate space on
6 the errata sheet for any corrections that are made.

7 After doing so, please sign the
8 errata sheet and date it. It will be attached to
9 your deposition.

10 It is imperative that you return the
11 original errata sheet to the deposing attorney
12 within thirty (30) days of receipt of the deposition
13 transcript by you. If you fail to do so, the
14 deposition transcript may be deemed to be accurate
15 and may be used in court.

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1
2 ACKNOWLEDGMENT OF DEPONENT
3

4 I, _____, do hereby
5 certify that I have read the foregoing pages, 1 -
6 282, and that the same is a correct transcription of
7 the answers given by me to the questions therein
8 propounded, except for the corrections or changes in
9 form or substance, if any, noted in the attached
10 Errata Sheet.
11
12

13 _____
14 DANIEL F. BURKLEY, MS

DATE

15
16
17 Subscribed and sworn
to before me this

18 ____ day of _____, 20____.

19 My commission expires: _____
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21 _____

21 Notary Public
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